

MARINE ENVIRONMENT PROTECTION
COMMITTEE
67th session
Agenda item 2

MEPC 67/2/4
25 June 2014
Original: ENGLISH

HARMFUL AQUATIC ORGANISMS IN BALLAST WATER

Report of the twenty-eighth meeting of the GESAMP-Ballast Water Working Group

Note by the Secretariat

SUMMARY

<i>Executive summary:</i>	This document contains the report of the twenty-eighth meeting of the GESAMP-Ballast Water Working Group (GESAMP-BWWG) and includes the evaluation of proposals submitted for approval by Japan and the Republic of Korea ¹
<i>Strategic direction:</i>	7.1
<i>High-level action:</i>	7.1.2
<i>Planned output:</i>	7.1.2.4
<i>Action to be taken:</i>	Paragraph 3
<i>Related document:</i>	GESAMP-BWWG 28/6 (attached)

Introduction

1 The twenty-eighth meeting of the GESAMP-Ballast Water Working Group (GESAMP-BWWG) was held at IMO Headquarters from 5 to 9 May 2014 and its report is attached to this document as GESAMP-BWWG 28/6.

2 The main purpose of this meeting was to review the proposals for approval of ballast water management systems that make use of Active Substances to treat ballast water prior to discharge into the marine environment. The findings of the Group are contained in annexes 4, 5 and 6 of the attached report.

¹ Following the decision of MEPC 58, only the main body of the GESAMP-BWWG report is translated in all three working languages with the annexes being submitted in English only.

Action requested of the Committee

3 The Committee is invited to:

- .1 agree that Final Approval be granted to the MARINOMATE™ Ballast Water Management System submitted by the Republic of Korea in document MEPC 67/2;
- .2 agree that Final Approval be granted to the BlueZone™ Ballast Water Management System submitted by the Republic of Korea in document MEPC 67/2/1;
- .3 agree that Final Approval be granted to the KURITA™ Ballast Water Management System submitted by Japan in document MEPC 67/2/2;
- .4 note that, as the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water is to be considered a living document, and as better data for some chemicals has become available since the publication of document MEPC 65/INF.14, some of the data used in the Final Approval evaluations differ from that used for Basic Approval;
- .5 recommend that applicants report all bromate species as bromate ion; and
- .6 approve the report in general.

**REPORT OF THE TWENTY EIGHTH MEETING OF THE GESAMP-BALLAST WATER
WORKING GROUP (GESAMP-BWWG)**

Table of Contents

No.	Section	Page Number
1	INTRODUCTION	3
2	ISSUES OF CONFIDENTIALITY	3
3	TERMS OF REFERENCE AND TIME FRAME	4
4	REVIEW OF PROPOSALS FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES	5
5	ANY OTHER BUSINESS	8
6	CONSIDERATION AND ADOPTION OF THE REPORT	8
	GLOSSARY OF TERMS AND DEFINITIONS	9
	LIST OF ABBREVIATIONS AND ACRONYMS	12

ANNEXES

- | | |
|---------|---|
| Annex 1 | List of members who attended the twenty-eighth meeting of the GESAMP-BWWG |
| Annex 2 | Agenda for the twenty-eighth meeting of the GESAMP-BWWG |
| Annex 3 | Terms of reference for the Technical Group (GESAMP-BWWG) |
| Annex 4 | Review of proposals for approval of Ballast Water Management Systems that make use of Active Substances – MARINOMATE™ Ballast Water Management System (previously known as "KTM-BWMS")
– Submitted by the Republic of Korea for Final Approval |
| Annex 5 | Review of proposals for approval of Ballast Water Management Systems that make use of Active Substances – BlueZone™ BWMS
– Submitted by the Republic of Korea for Final Approval |
| Annex 6 | Review of proposals for approval of Ballast Water Management Systems that make use of Active Substances – KURITA™ Ballast Water Management System
– Submitted by Japan for Final Approval |

1 INTRODUCTION

1.1 The twenty-eighth meeting of the GESAMP-Ballast Water Working Group (GESAMP-BWWG) was held at IMO Headquarters, London, from 5 to 9 May 2014 under the chairmanship of Mr. Jan Linders. A list of members who attended this meeting is shown in annex 1 and the agenda, as adopted by the Group, is set out in annex 2 of this report.

1.2 The meeting was opened by Mr. Markus Helavuori, Technical Officer, Marine Environment Division, who expressed appreciation for the efforts made by the members of the GESAMP-BWWG to attend this meeting.

1.3 The Secretariat reiterated the need to expand the membership of the Group in such a way that experts with specific expertise could be invited when specific knowledge is required or when the current members are unavailable. In this respect, the Group was again requested to recommend suitable experts that could be contacted by the Secretariat/GESAMP, bearing in mind the need for a fair and proper geographic representation. In this context, the Group agreed to review the GESAMP Pool of Experts for potential new members.

1.4 The Secretariat stated that it will continue to make every effort to further expand the membership of the Group to ensure a smooth and effective evaluation of the proposals for approval submitted by the IMO Member States.

1.5 Referring to the workload of the Group and the importance and need for timely review of the proposals for approval, the Group, supported by the Secretariat, made every effort to handle submissions in a timely manner and to respond to all the proposals.

1.6 The Secretariat expressed its appreciation for the effort made by the IMO consultant, Mrs. Annette Dock, for her hard work in preparing this meeting and in reviewing a large amount of documentation in a very short period of time.

1.7 Finally, the Secretariat reported on the contractual arrangements and informed the Group on the logistics of the meeting.

2 ISSUES OF CONFIDENTIALITY

2.1 Three proposals for Final Approval and one proposal for Basic Approval of ballast water management systems that make use of Active Substances (MEPC 67/2, MEPC 67/2/1, MEPC 67/2/2 and MEPC 67/2/3) were put on the meeting agenda. All four submissions contained confidential supporting data.

2.2 The confidential nature of the information was recognized by the Group and was treated as such in order to protect the commercial interests of the manufacturers concerned. The Group noted that the Secretariat would liaise with the relevant Administrations prior to submitting the report to MEPC to ensure that the report does not contain any confidential information. The Group, however, recalled that all information related to safety and environmental protection, including physical/chemical properties, environmental fate and toxicity, should be treated as non-confidential.

2.3 Pursuant to paragraphs 4.2.2, 8.1.1 and 8.1.2.7 of the *Procedure for approval of ballast water management systems that make use of Active Substances (G9)*, all information gathered, materials, notes and reports obtained or made out during the work of the GESAMP-BWWG, were, and will be, treated as confidential. In this respect, all the

members of the Group and the IMO consultant were reminded of the content of their Statements of Acceptance related to confidentiality.

2.4 The submissions (dossiers) were kept in a safe place in the IMO Headquarters and made available to the members of the Group and IMO consultant during the working hours.

2.5 On completion of the work, the Chairman of the GESAMP-BWWG collected from the other members of the Group all the documents, drafts and any other associated records and reports, which were handed over to the IMO Secretariat of the GESAMP-BWWG for retention in confidence. The members undertook to destroy all electronic records and data held on personal computers/laptops after completion of the work.

3 TERMS OF REFERENCE AND TIME FRAME

3.1 The Group continued to conduct its work in accordance with the terms of reference approved by the MEPC as contained in annex 3 of this report.

3.2 The Group used the table below to determine the timetable for activities related to its regular meetings and agreed to decide, on a case-by-case basis, on the timing of additional meetings as appropriate.

TIMETABLE FOR ACTIVITIES RELATED TO GESAMP-BWWG MEETINGS

Timeline	Activity
28 weeks before MEPC	Deadline for submission of application dossiers and related documents to be reviewed by the GESAMP-BWWG
(8 weeks)	Preparation of the meeting, including circulation of any relevant information provided by other delegations
20 weeks before MEPC	GESAMP-BWWG Meeting
(1 week)	Editing and completion of the draft report of the meeting
(3 weeks)	Review and approval of the report by the GESAMP including response/clarification by the working group
(1 week)	Administrations confirm that no confidential data are contained in the report
(1 week)	Produce the final report addressing the comments by the GESAMP
13 weeks before MEPC	Submission of the report of the meeting of the GESAMP-BWWG in accordance with the 13-week deadline (bulky documents) for MEPC

3.3 Aware that four proposals for approval had been submitted for consideration by MEPC 67 in accordance with the agreed deadline of 11 April 2014, three of which were evaluated at this meeting, the Group confirmed that an additional meeting (i.e. the twenty-ninth meeting) will be held on 8 July 2014.

3.4 Bearing in mind that MEPC 68 is tentatively scheduled from 11 to 15 May 2015 and considering the activities presented in the table above, the Group agreed to tentatively schedule its thirtieth meeting for 8 to 12 December 2014 with a deadline for submission of documents on 24 October 2014.

3.5 Recognizing the possibility that more than four proposals may be submitted for its review and approval by MEPC 68, the Group expressed its availability to have an additional meeting (GESAMP-BWWG 31), tentatively scheduled for February 2015 to accommodate as many proposals as possible provided that all the necessary conditions for organizing such a meeting are met.

4 REVIEW OF PROPOSALS FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES

4.1 Applicable Methodology

4.1.1 The Group recalled that MEPC 63 decided that the revised Methodology for information gathering and conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.1) should be applied to all submissions for Basic Approval to MEPC 65 and onwards. The Group recalled that the main reason for use of the Methodology is to facilitate the Group's work and to improve the efficiency of evaluation and also to facilitate the preparation of the dossiers by the applicants.

4.1.2 The twenty-eighth session of the GESAMP-BWWG had for its consideration one submission for Basic Approval and three submissions for Final Approval, all of which had used the revised Methodology.

4.1.3 The Group recognized that the submissions for Final Approval had utilized data from the GESAMP-BWWG Database of chemicals most frequently associated with treated ballast water, as presented in document MEPC 65/INF.14. The Group noted that, as the Database is to be considered a living document, and as better data for some chemicals has become available since the publication of MEPC 65/INF.14, some of the data used in the Final Approval evaluations differs from that used for Basic Approval.

4.1.4 The Group noted that the Database includes three bromate substances (i.e. bromate ion, potassium bromate and sodium bromate). In ballast water, bromate exists as bromate ion and is measured as an ion by the current analytical methods. For consistency, the Group concluded that bromate ion will be used for all bromate species in its risk assessments and recommended that applicants in the future only report bromate as bromate ion.

4.1.5 The Group noted that MEPC 66 had endorsed a new version of the Methodology (BWM.2/Circ.13/Rev.2) applicable to all submissions for Basic Approval to MEPC 69 and onwards, and subsequent submissions for Final Approval of those systems. The Group, however, noted with appreciation, that proponents were recommended to make use of revision 2, and in particular the GESAMP-BWWG Database of 43 chemicals most commonly associated with treated ballast water, at their earliest opportunity.

4.1.6 The Group noted, that the new revision of the Methodology, states that it is not necessary to undertake further assessment of temperature effects on the degradation rate of Active Substances and Relevant Chemicals if the PEC/PNEC ratio is found to be acceptable assuming no degradation. The Group recalled that no degradation is assumed also in the MAMPEC-BW model, already used by the Group.

4.2 Detailed review of the submissions

4.2.1 The details of the submissions included in the agenda of this meeting are as follows:

Annex	BWMS	Administration
4	MARINOMATE™ Ballast Water Management System (previously known as the "KTM-BWMS") (Final Approval)	Republic of Korea
5	BlueZone™ Ballast Water Management System (Final Approval)	Republic of Korea
6	KURITA™ Ballast Water Management System (Final Approval)	Japan

4.2.2 The Group noted that no face-to-face meetings were requested by Administrations for the twenty-eighth meeting of the GESAMP-BWWG.

4.2.3 Bearing in mind the criteria associated with Procedure (G9) and having reviewed all of the information related to these submissions, the Group recommended that:

- .1 Final Approval be granted to the MARINOMATE™ Ballast Water Management System (Republic of Korea);
- .2 Final Approval be granted to the BlueZone™ Ballast Water Management System (Republic of Korea);
- .3 Final Approval be granted to the KURITA™ Ballast Water Management System (Japan); and
- .4 although every effort was made to evaluate the ElysisGuard Ballast Water Management System (Singapore) at this meeting, the Group was only able to complete the evaluation of the first three proposals because of lack of time.

4.3 Specific comments related to the MARINOMATE™ Ballast Water Management System

4.3.1 The Group noted that the MARINOMATE™ Ballast Water Management System (BWMS) uses in situ electrolysis using seawater to produce the Active Substance TRO to treat the ballast water. The Group further noted that the system is equipped with a plankill pipe™ unit which damages zooplanktons by physical effects of collision and turbulence before electrolysis. It has been submitted by the Republic of Korea for Final Approval.

4.3.2 The Group recalled that Basic Approval for the ballast water management system (BWMS) was granted by MEPC 64 (under the name of KTM-Ballast Water Management System) and the report is available as document MEPC 64/2/6, annex 5.

4.3.3 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the MARINOMATE™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of

the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

TRO: 10.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of salinity: ≥ 8 PSU.

Applicable range of temperature: > 4°C.

4.4 **Specific comments related to the BlueZone™ Ballast Water Management System**

4.4.1 The Group noted that the BlueZone™ BWMS has been developed by Sunbo Industries Co. Ltd., DSEC Co. Ltd., and the Korean Institute of Machinery and Material (KIMM) and uses the Active Substance ozone, in the form of micro-ozone bubbles (< 50 µm in diameter), to treat the ballast water at uptake. An ozone generator is employed to produce the Active Substance. It has been submitted by the Republic of Korea for Final Approval.

4.4.2 The Group recalled that Basic Approval for this BWMS was granted by MEPC 65 and the report is available as document MEPC 65/2/19, annex 6.

4.4.3 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the BlueZone™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

Ozone gas dose: 2.5 mg/L as O₃

TRO: 2.3 mg/L (as Cl₂); and

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂).

4.5 **Specific comments related to the KURITA™ Ballast Water Management System**

4.5.1 The Group noted that the KURITA™ BWMS uses the Active Substance sodium hypochlorite to treat the ballast water during uptake. The Group further noted that the applicant intends to provide two different kinds of Active Substance solutions, one with a

small amount of phosphate as a corrosion inhibitor added and one Active Substance solution without phosphate. It has been submitted by Japan for Final Approval.

4.5.2 The Group recalled that Basic Approval for the ballast water management system (BWMS) was granted by MEPC 66 and the report is available as document MEPC 66/2/10, annex 4.

4.5.3 Having reviewed all the data and information submitted by Japan with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the KURITA™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – the maximum dose for the Active Substance should be set as follows:

TRO: 20.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance** – the system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of temperature: > 4°C.

5 ANY OTHER BUSINESS

- 5.1 No other business was discussed.

6 CONSIDERATION AND ADOPTION OF THE REPORT

- 6.1 The draft report of the twenty-eighth meeting of the GESAMP-BWWG was produced on Friday 9 May 2014 and, after a paragraph-by-paragraph review, the Group agreed on the final text and requested the Secretariat to make the necessary editorial changes to ensure consistency with IMO documents' format and style.

GLOSSARY OF TERMS AND DEFINITIONS

Active Substance (AS) means a substance or organism, including a virus or a fungus that has a general or specific action (chemical or biological) on or against harmful aquatic organisms and pathogens.

Acute (eco)toxicity is the ability of a substance to cause adverse effects within a short period following exposure.

Administration means the government of the state under whose authority the ship is operating.

Ballast water means water with its suspended matter taken on board a ship to control trim, list, draught, stability or stresses of the ship.

Ballast water management means mechanical, physical, chemical and biological processes – either singularly or in combination – to remove, render harmless, or avoid the uptake or discharge of harmful aquatic organisms and pathogens within ballast water and sediments.

Ballast Water Management Convention (the Convention) means the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004.

Ballast water management system (BWMS) means any system which processes ballast water such that it meets or exceeds the ballast water performance standard in the Convention. The BWMS includes ballast water treatment equipment, all associated control equipment, monitoring equipment and sampling facilities.

Ballast water tank is any tank, hold or space used for the carriage of ballast water.

Basic Approval (BA) means the preliminary approval of Active Substances and the ballast water management system that uses them in order to comply with the Ballast Water Management Convention. Basic Approval should confirm that the available information does not indicate possible unacceptable adverse effects or a potential for unreasonable risk to environment, human health, property or resources. This should include consideration of potential risks associated with the Active Substance during full-scale deployment on commercial ships when possible.

Bioaccumulation (B) is the progressive increase in the amount of a substance in an organism or tissue which occurs because the rate of intake exceeds the organism's ability to remove the substance.

Chronic (eco)toxicity is the capacity for a substance to produce adverse effects following longer term exposure or to produce effects which persist.

Control sample is that from a test to which no substance was applied.

Degradation is the process by which a substance is broken down to simpler structures through biodegradation or abiotic mechanisms.

DPD method is the colorimetric analytical method based on use of the reagent DPD (N, N-diethyl-p-phenylenediamine) where oxidants such as chlorine react with DPD causing a deep-purple colour to form with an intensity proportional to the oxidant concentration. The oxidant concentration (mg/L) in the test water is then determined as the absorbance of light in a colorimetric flow cell.

Exposure is the concentration or amount of a substance that reaches the target organism, usually expressed in numerical terms of concentration, duration and frequency.

Final Approval (FA) means the approval of a ballast water management system using an Active Substance or Preparation to comply with the Convention and includes an evaluation of the whole effluent toxicity (WET) tests performed as part of the land-based Type Approval process in accordance with the Guidelines for approval of ballast water management systems (G8). The review does not include the re-evaluation of efficacy testing results conducted by Administrations under the Guidelines (G8). The Final Approval should confirm that previous evaluations of risks to ship, crew and the environment including storage, handling and application of Active Substances or Preparations remain valid and the concerns expressed during the Basic Approval process have been addressed, as well as that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval.

GESAMP is the IMO/FAO/UNESCO-IOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, an advisory and multi-disciplinary body consisting of specialized experts nominated by the sponsoring agencies. Experts working for the GESAMP act independently in their individual capacity.

GESAMP-Ballast Water Working Group (GESAMP-BWWG), also being referred to as the Group, means the Technical Group consisting of independent experts acting in their individual capacity that review the proposals for approval of ballast water management systems that make use of Active Substances submitted by the Administration and report, through the GESAMP, to MEPC. When reviewing the proposals, the Group should take account of any other relevant data as well as other relevant information submitted to it, or the Group is aware of, because of its members' expertise.

Hazard is the set of inherent properties of a substance which gives potential for adverse effects, and depending on the level of exposure.

Lower Explosive Limit (LEL) is the lowest concentration (percentage) of a gas or a vapour in air capable of producing a flash of fire in presence of an ignition source (arc, flame, heat).

Median effective/lethal concentration/dose (EC_{50} , LC_{50} , LD_{50}) is the statistically derived concentration/dose of a substance expected to produce a certain effect/kill 50% of test organisms in a given population under defined conditions.

No-observable/adverse-effect-concentration/level (NOEC, NOEL, NOAEC, NOAEL) is the highest concentration or amount of a substance that causes no observable/adverse biological effect to the target organism.

Organization means the International Maritime Organization (IMO).

Other Chemical (OC) means any other substances, other than the Active Substance(s) or Relevant Chemicals, potentially associated with the system either intentionally or resulting from the treatment of ballast water.

Persistence (P) is the residence time of a substance in a defined environmental compartment such as soil, seawater, fresh water, etc.

Predicted environmental concentration (PEC) is the predicted concentration of a substance within an environmental compartment such as seawater.

Predicted no-effect concentration (PNEC) is an estimated no observable effect concentration for an aquatic species based on extrapolated experimental data.

Relevant Chemical (RC) means transformation or reaction products that are produced during and after employment of the ballast water management system in the ballast water or in the receiving environment and that may be of concern to the ship's safety, aquatic environment and/or human health.

Risk is the probability of any defined hazard occurring from exposure to a substance under specific conditions. Risk is a function of the likelihood of exposure and the likelihood to produce adverse effects.

Sampling facility is that place in the ballast water piping where the sample is taken.

Sediments means matter settled out of ballast water within a ship.

Ship means a vessel of any type whatsoever operating in the aquatic environment.

Toxicity (T) is the adverse effect of a substance on an organism.

Treatment rated capacity (TRC) is the maximum continuous capacity expressed in cubic metres per hour for which the BWMS is Type Approved.

Trophic level is the grouping together of functionally similar organisms based on similarities in the patterns of food production and consumption amongst the different organisms.

Type Approval is granted to a BWMS that meets a minimum set of regulatory, technical and safety requirements. Generally, Type Approval is required before a system is allowed to be sold in a particular country.

LIST OF ABBREVIATIONS AND ACRONYMS

<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
AS	Active Substance(s)
B	bioaccumulation
BWMS	ballast water management system
BWWG	Ballast Water Working Group
°C	degree Celsius (Centigrade)
CMR	carcinogenicity, mutagenicity and reproductive toxicity
CV	Coefficient of Variation
d	day(s)
DBP	disinfection by-product(s)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
DOC	dissolved organic carbon
DPD	N,N-diethyl-p-phenylenediamine
EC ₅₀	effect concentration, 50% (median effective concentration)
EU	European Union
g	gram
Guidelines (G8)	Guidelines for approval of ballast water management systems.
Procedure (G9)	Procedure for approval of ballast water management systems that make use of Active Substances (G9), as revised, adopted by resolution MEPC.169(57) in April 2008
h	hour(s)
HAA	Haloacetic acid(s)
ICRAM	Central Institute for Applied Marine Research
IMDG	International Maritime Dangerous Goods (Code)
IMO	International Maritime Organization
ISO	International Organization for Standardization
kg	kilogram
L	litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	lethal dose, 50%
LEL	lower explosive limit
MAD	maximum allowable dose
MADC	maximum allowable discharge concentration
MAMPEC	Marine Antifoulant Model for PEC calculation

MAMPEC-BW	Marine Antifoulant Model for PEC calculation for Ballast Water
MEPC	Marine Environment Protection Committee
mg	milligram
ml	millilitre
NA	Not applicable or Not available
NOAEC	No Observed Adverse Effect Concentration
NOEC	No Observed Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
OC	Other Chemical(s)
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Level
ORP	oxidation-reduction (redox) potential
P	Persistence
PBT	Persistence, Bioaccumulation and Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
POC	Particulate organic carbon
POM	Particulate organic matter
PPE	Personal protective equipment
PSC	Port State Control
PSU	Practical salinity unit
QA/QC	Quality Assurance/Quality Control
RAR	Risk Assessment Report
RC	Relevant Chemical(s)
RCR	Risk Characterization Ratio
RPE	Respiratory protective equipment
T	Toxicity
THM	Trihalomethane(s)
TOC	Total organic carbon
TRC	Treatment rated capacity
TRO	total residual oxidant
TSS	Total suspended solids
UEL	upper explosive limit
US EPA	United States Environmental Protection Agency
UV	Ultraviolet
WET	Whole Effluent Toxicity test(s)/testing
wt	Weight

ANNEX 1

**TWENTY-EIGHTH SESSION OF THE
GESAMP-BALLAST WATER WORKING GROUP
(IMO London, 5 to 9 May 2014)**

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ANNEX 2

AGENDA FOR THE TWENTY-EIGHTH MEETING OF THE GESAMP-BALLAST WATER WORKING GROUP

- 1 Introduction
- 2 Issues of confidentiality
- 3 Terms of reference and time frame
- 4 Review of proposals for approval of ballast water management systems that make use of Active Substances
 - .1 Republic of Korea: **MARINOMATE™ BWMS**
For Final Approval
 - .2 Republic of Korea: **BlueZone™ BWMS**
For Final Approval
 - .3 Japan: **KURITA™ BWMS**
For Final Approval
 - .4 Singapore: **ElysisGuard BWMS**
For Basic Approval
- 5 Any other business
- 6 Consideration and adoption of the report

ANNEX 3

TERMS OF REFERENCE FOR THE TECHNICAL GROUP (GESAMP-BWWG)

1 Consideration of development of necessary methodologies and information requirements in accordance with the "Procedure for approval of ballast water management systems that make use of Active Substances (G9)" for consideration by MEPC 67.

2 For Basic Approval, the Group should review the comprehensive proposal submitted by the Members of the Organization, along with any additional data submitted, as well as other relevant information available to the Group and report to the Organization. In particular, the Group should undertake:

- .1 scientific evaluation of the data-set in the proposal for approval (see paragraphs 4.2, 6.1, 8.1.2.3 and 8.1.2.4 of Procedure (G9));
- .2 scientific evaluation of the assessment report contained in the proposal for approval (see paragraph 4.3.1 of Procedure (G9));
- .3 scientific evaluation of the risks to the ship and personnel to include consideration of the storage, handling and application of the Active Substance (see paragraph 6.3 of Procedure (G9));
- .4 scientific evaluation of any further information submitted (see paragraph 8.1.2.6 of Procedure (G9));
- .5 scientific review of the risk characterization and analysis contained in the proposal for approval (see paragraph 5.3 of Procedure (G9));
- .6 scientific recommendations on whether the proposal has demonstrated a potential for unreasonable risk to the environment, human health, property or resources (see paragraph 8.1.2.8 of Procedure (G9)); and
- .7 preparation of a report addressing the above-mentioned aspects for consideration by the MEPC (see paragraph 8.1.2.10 of Procedure (G9)).

3 For Final Approval, the Group should review the discharge testing (field) data and confirm that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval and that the previous evaluation of the risks to the ship and personnel including consideration of the storage, handling and application of the Active Substance remains valid. The evaluation will be reported to the MEPC (see paragraph 8.2 of Procedure (G9)).

4 The Group shall keep confidential all data, the disclosure of which would undermine protection of the commercial interests of the applicant, including intellectual property.

ANNEX 4

REVIEW OF PROPOSALS FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES

MARINOMATE™ Ballast Water Management System

(consisting of plankill pipe™ unit, disinfection with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium thiosulfate)

Submitted by the Republic of Korea for Final Approval

0 SUMMARY

0.1 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the MARINOMATE™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

TRO: 10.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of salinity: ≥ 8 PSU.

Applicable range of temperature: > 4°C.

0.2 The Group recalled that Basic Approval for the BWMS was granted by MEPC 64 (under the name of KTM-Ballast Water Management System) and the report is available in document MEPC 64/2/6, annex 5.

0.3 The Group noted that the MARINOMATE™ Ballast Water Management System (BWMS) uses in situ electrolysis using seawater to produce the Active Substance TRO to treat the ballast water. The Group further noted that the system is equipped with a plankill pipe™ unit which damages zooplanktons by physical effects of collision and turbulence before electrolysis.

0.4 The Group noted that the applicant has proposed an intermittent recirculation system with an anti-fouling function to maintain the efficacy of the plankill pipe™ unit during ballast operation.

0.5 Due to the in situ preparation of the Active Substance TRO by electrolysis, hydrogen would be formed as by-product. The Group noted that the applicant will install a degas function for hydrogen gas at shipboard testing prior to type approval.

0.6 As the BWMS requires the storage of neutralizer sodium thiosulfate in a 25% solution on board ship, the Group verified and concluded that all risk mitigation measures have been put in place related to the storage and that loading of the sodium thiosulfate neutralizing solution to the BWMS had been fully detailed in the operating manual for this system.

0.7 The Group recognized that the system utilized an Active Substance with potential safety and environmental concerns and the Group reviewed the hazards and risks associated with the Active Substance.

0.8 The Group recognized that the applicant had provided information on system controls and safety considerations for installation of the BWMS on board, together with provisions for maintenance and emergency operations of the system. As such, the Group considered that sufficient information had been supplied for the purposes of Final Approval evaluation.

0.9 The Group noted that the applicant had performed corrosion testing and the results of this testing indicated that no additional corrosive effect on usual ship construction materials was observed.

0.10 The Group further noted that analytical results for the Active Substance and Other Chemicals in treated ballast water had been provided.

0.11 The Group noted that the applicant had carried out a risk assessment for the crew and the general public based on the Methodology (BWM.2/Circ.13/Rev.1). The Group concluded that there should be no unacceptable risks to human health arising from the use as proposed of this BWMS.

0.12 The Group noted that the applicant had calculated the PEC values of the Relevant Chemicals present in ballast water discharged from the system that were determined using the MAMPEC-BW model version 3.0. Based on the established PEC/PNEC ratios, the Group would expect slight risks for aquatic organisms but an additional dilution factor of 3 to 4 would eliminate these risks. The Group considered that based on these results no unacceptable risk for aquatic organisms is anticipated from the normal use of this BWMS.

0.13 The Group noted that the applicant had provided information on ecotoxicity testing of treated ballast water and carried out an environmental risk assessment for aquatic organisms based on the calculation of PEC/PNEC ratios. Based on these two approaches the Group concluded that there should be no unacceptable risks to the environment by the use of this BWMS, which should be verified to the satisfaction of the Administration before issuance of the Type Approval Certificate.

0.13 In conclusion, having reviewed all the information provided by the applicant, the Group agreed to recommend to the MEPC that Final Approval be granted to the MARINOMATE™ BWMS.

1 INTRODUCTION

1.1 The data used to evaluate this BWMS were extracted from that supplied by the Republic of Korea in document MEPC 67/2, supplemented by the information contained

in the confidential application dossier, together with additional information provided by the applicant after a request for further information by the Group during its meeting.

2 DESCRIPTION OF THE SYSTEM

2.1 The Group noted that figure 1 schematically shows the BWMS being reviewed for Final Approval. The BWMS combines destruction of biota at uptake of ballast water using a plankill pipe™ unit followed by a disinfection step, based on electrolysis of seawater to produce Active Substance TRO for the treatment of remaining microorganisms. During uptake of ballast water, the electrolysis unit generates disinfectants directly from the seawater to treat the ballast water. The target level of TRO concentration produced by the MARINOMATE™ BWMS is 10 mg TRO/L as Cl_2 . During deballasting, the discharge water is monitored by a TRO sensor, and a feedback control system controls the dosage of neutralizing solution into the deballasting pipeline to maintain a TRO concentration of less than 0.2 mg/L as Cl_2 in the discharge water.

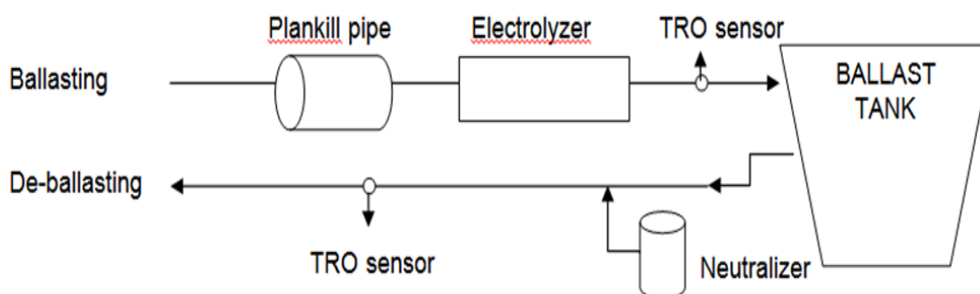


Figure 1: Schematic process diagram of BWMS

2.2 The Group recalled that the electrolysis unit of this BWMS is mounted directly in the main ballast pipeline and is therefore a full flow system. The operation of the electrolyser unit is controlled by a TRO sensor through a feedback system to the control unit which in turn adjusts the power supply to maintain the required TRO concentration as 10 mg/L.

2.3 The Group noted that the applicant will install a degas function for hydrogen gas at shipboard testing prior to type approval.

2.4 The Group noted that the system is monitored continuously during operation by TRO detectors installed to measure TRO concentrations of treated water and of neutralized water to be discharged. The Group further noted that the dosage level of TRO reported for both the land-based tests with marine and brackish water was maintained between 9 and 10 mg/L. However, the Group identified some fluctuation from these parameters. The applicant stated in their response that the fluctuation may have resulted from interference arising from air bubbles during TRO monitoring. Therefore, the Group recommended that further TRO monitoring improvement be sought by the applicant, including the possible change of the sampling point for monitoring.

2.5 The Group noted that sodium thiosulfate as 25% aqueous solution is to be stored on-board and will be injected into the ballast water before deballasting. The injection is controlled by a TRO sensor and the control unit so the TRO concentration of the discharged water is below 0.2 mg TRO/L as Cl_2 .

2.6 The Group further noted that by overdosing the neutralizer at the beginning of deballasting the TRO concentration was kept at 0.2 mg TRO/L as Cl_2 during the land-based test.

2.7 The Group noted that the system with the intended dose operates at 4°C and 8 PSU. Therefore, the Group concluded that the BWMS has a system limitation of salinity at ≥ 8 PSU as measured by a conductivity meter. The Group, however, recommended the use of a salinity meter for this purpose.

2.8 The Group noted that the applicant has proposed an intermittent recirculation system with an anti-fouling function to maintain the efficacy of the plankill pipe™ unit during the ballast operation. The Group also noted that the applicant has provided details of this recirculation system where the Active Substance, generated by the electrolyser, is being transferred back into the inlet of the plankill pipe™ unit in a concentration of 0.5 mg TRO/L, using a 5% feedback on a volume basis. The Group was able to accept the applicant's intermittent approach based on the detailed chemical analysis provided.

3 CHEMICALS ASSOCIATED WITH THE SYSTEM

3.1 The Group noted that in this BWMS the Active Substance is expressed as TRO, the Relevant Chemicals are the disinfection by-products (DBP), while the Other Chemical is the neutralization agent sodium thiosulfate.

3.2 The Group noted that the applicant has provided analyses of treated ballast water for Active Substance and Other Chemicals as part of this application for Final Approval.

3.3 The Group noted that the results of chemical analysis of the ballast water samples both before and after the neutralization process from this BWMS are provided in tables 1, 2 and 3.

Table 1: RCs produced by the BWMS in seawater

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
Bromate	0.22	N.D.	N.D.	191	N.D.	80.9	N.D.	24.3
				132		64.5		19.7
Bromochloroacetic acid	0.58	N.D.	N.D.	4.32	N.D.	5.75	N.D.	6.98
				3.97		5.42		6.76
Bromochloroacetonitrile	0.01	N.D.	N.D.	0.35	N.D.	0.33	N.D.	0.49
				0.13		0.24		0.39
Bromodichloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Chloral hydrate	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Chloropicrin	0.01	N.D.	N.D.	0.07	N.D.	0.29	N.D.	0.42
				0.05		0.34		0.49
Dalapon	0.61	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	1.01
				N.D.		N.D.		0.84
Dibromoacetic acid	0.55	N.D.	N.D.	15.3	N.D.	43.4	N.D.	68.7
				9.48		47.3		62.6
Dibromoacetonitrile	0.01	N.D.	N.D.	2.26	N.D.	3.70	N.D.	6.03
				2.07		3.41		5.17
Dibromochloroacetic acid	0.53	N.D.	N.D.	13.5	N.D.	16.7	N.D.	19.5

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
				12.2		17.2		18.0
Dibromochloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Dibromochloromethane	0.37	N.D.	N.D.	1.42	N.D.	4.57	N.D.	6.08
				1.01		3.04		5.58
Dichloroacetic acid	0.57	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Dichloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Dichlorobromoacetic acid	0.53	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Dichlorobromomethane	0.24	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
1,2-Dichloroethane	0.18	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
1,2-Dichloropropane	0.09	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Monobromoacetic acid	0.80	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Monobromoacetonitrile	0.01	N.D.	N.D.	0.56	N.D.	1.34	N.D.	1.39
				0.20		1.59		1.83
Monochloroacetic acid	0.88	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Monochloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Tribromoacetic acid	0.57	N.D.	N.D.	53.2	N.D.	204	N.D.	257
				40.4		219		208
Tribromoacetonitrile	0.02	N.D.	N.D.	0.20	N.D.	0.37	N.D.	0.54
				0.13		0.26		0.49
Tribromomethane	0.58	N.D.	N.D.	131	N.D.	256	N.D.	384
				96.9		227		331
Trichloroacetic acid	0.54	8.49	6.91	16.6	8.07	45.1	4.32	6.28
				7.16		1.11		N.D.
Trichloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Trichloromethane	0.32	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Trichloropropane	0.30	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.

^a: Detection limit mg/L.

^b: After neutralization.

N.D. Not detected.

Table 2: RCs produced by the BWMS in brackish water

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
Bromate	0.22	N.D.	N.D.	66.9 42.7	N.D.	32.0 20.5	N.D.	21.2 15.9
Bromochloroacetic acid	0.58	N.D.	N.D.	N.D. N.D.	3.72	N.D. N.D.	1.78	N.D. N.D.
Bromochloroacetonitrile	0.01	0.07	0.06	0.65 0.27	N.D.	0.64 0.35	N.D.	0.50 0.39
Bromodichloroacetonitrile	0.01	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Chloral hydrate	0.01	3.25	3.72	7.54 7.87	1.14	2.03 2.13	N.D.	0.44. 0.49
Chloropicrin	0.01	N.D.	N.D.	0.13 0.10	N.D.	0.37 0.39	N.D.	0.46 0.50
Dalapon	0.61	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	0.85 0.89
Dibromoacetic acid	0.55	0.73	1.39	5.73 4.02	1.68	23.2 24.7	2.75	35.0 33.7
Dibromoacetonitrile	0.01	N.D.	N.D.	4.44 3.17	N.D.	5.92 5.06	N.D.	9.62 8.42
Dibromochloroacetic acid	0.53	N.D.	N.D.	N.D. N.D.	1.60	2.00 1.50	1.08	2.79 2.29
Dibromochloroacetonitrile	0.01	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Dibromochloromethane	0.37	N.D.	N.D.	2.26 2.38	N.D.	9.88 7.80	N.D.	13.9 10.5
Dichloroacetic acid	0.57	1.24	1.20	1.74 1.75	1.38	2.90 3.03	1.42	5.18 5.11
Dichloroacetonitrile	0.01	1.74	1.66	2.12 1.67	1.05	0.08 0.05	0.25	0.05 0.03
Dichlorobromoacetic acid	0.53	9.10	8.41	9.26 9.18	N.D.	10.2 10.1	N.D.	23.7 21.4
Dichlorobromomethane	0.24	N.D.	N.D.	3.66 1.21	N.D.	3.15 2.58	N.D.	3.10 2.51
1,2-Dichloroethane	0.18	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
1,2-Dichloropropane	0.09	N.D.	N.D.	1.84 1.31	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Monobromoacetic acid	0.80	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Monobromoacetonitrile	0.01	N.D.	N.D.	0.28 0.15	N.D.	1.26 1.33	N.D.	2.45 1.78
Monochloroacetic acid	0.88	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Monochloroacetonitrile	0.01	N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.	N.D.	N.D. N.D.
Tribromoacetic acid	0.57	N.D.	N.D.	12.5 11.3	2.87	50.2 41.1	3.05.	47.6 40.0

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
Tribromoacetonitrile	0.02	N.D.	N.D.	0.59	N.D.	0.68	N.D.	1.01
				0.43		0.63		0.89
Tribromomethane	0.58	N.D.	N.D.	109	N.D.	222	N.D.	281
				74.3		188		211
Trichloroacetic acid	0.54	12.1	13.8	17.2	12.4	16.3	13.6	26.7
				14.8		16.5		28.9
Trichloroacetonitrile	0.01	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Trichloromethane	0.32	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.
Trichloropropane	0.30	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.

^a. Detection limit mg/L

^b. After neutralization.

N.D. Not detected.

3.4 The Group noted that the applicant also provided additional tests using water near to the system limitation of salinity (8 PSU). The results were presented in table 3.

Table 3: RCs produced by the BWMS in water at 8 PSU

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
Bromate	0.22	N.D.	N.D.	66.9	N.D.	32.0	N.D.	21.2
				42.7		20.5		15.9
Bromochloroacetic acid	0.58	N.D.	N.D.	N.D.	N.D.	2.28	0.65	2.77
				N.D.		2.19		2.66
Bromochloroacetonitrile	0.01	0.55	0.61	1.07	0.47	0.85	0.24	0.79
				0.62		0.67		0.84
Chloral hydrate	0.01	2.97	2.83	7.24	1.08	4.72	0.78	2.63
				8.30		4.05		3.11
Chloropicrin	0.01	N.D.	N.D.	0.25	N.D.	0.56	N.D.	0.69
				0.18		0.57		0.69
Dalapon	0.61	1.18	0.80	1.40	0.83	1.93	0.91	2.20
				0.96		2.13		2.36
Dibromoacetic acid	0.55	N.D.	N.D.	3.11	N.D.	20.9	2.55	23.4
				1.09		20.1		22.4
Dibromoacetonitrile	0.01	0.30	0.76	4.63	0.21	7.51	0.04	10.1
				4.11		6.38		9.33
Chlorodibromoacetic acid	0.53	N.D.	N.D.	N.D.	N.D.	2.03	N.D.	2.97
				N.D.		2.32		2.79
Dibromochloromethane	0.37	0.84	0.62	2.40	1.25	19.3	0.76	24.5
				1.65		16.3		24.2
Dichlorobromomethane	0.24	2.34	1.35	5.26	1.81	13.0	1.43	18.0

Ingredient (IUPAC name)	DL ^a	Day 0 (µg/L)			Day 1 (µg/L)		Day 5 (µg/L)	
		Test	Control	Treated	Control	Treated	Control	Before N
				After N ^b		After N		After N
				4.38		12.9		15.2
Dichloroacetic acid	0.57	1.74	1.60	2.62	2.28	5.24	2.99	5.76
				2.27		5.17		5.63
Dichloroacetonitrile	0.01	5.15	5.31	5.00	4.24	4.56	5.89	6.86
				4.90		5.26		5.90
Dichlorobromoacetic acid	0.53	N.D.	N.D.	0.60	0.67	1.58	0.61	2.51
				N.D.		1.89		2.40
1,2-Dichloropropane	0.09	N.D.	N.D.	2.11	N.D.	0.22	N.D.	N.D.
				0.45		0.27		N.D.
Monobromoacetonitrile	0.01	N.D.	N.D.	0.86	N.D.	0.90	N.D.	1.55
				0.97		0.90		1.66
Tribromoacetic acid	0.57	N.D.	N.D.	3.26	N.D.	18.9	N.D.	21.4
				0.94		22.4		20.3
Tribromoacetonitrile	0.02	N.D.	N.D.	0.48	N.D.	5.17	N.D.	0.26
				0.46		4.21		0.28
Tribromomethane	0.58	3.53	2.67	21.6	2.38	139	2.07	184
				17.5		108		122
Trichloroacetic acid	0.54	2.35	3.09	1.97	9.80	8.58	17.3	22.0
				2.37		17.4		21.1
Trichloromethane	0.32	10.7	8.45	25.9	5.49	16.4	N.D.	5.43
				20.2		11.8		4.47
Trichloropropane	0.30	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
				N.D.		N.D.		N.D.

a. Detection limit mg/L

b. After neutralization.

N.D. Not detected.

3.5 From tables 1, 2 and 3, the Group selected the substances in table 4 based on their maximum concentrations for further risk assessment for human health and the environment. These substances should be considered the Relevant Chemicals for this BWMS.

Table 4: Selected Relevant Chemicals and maximum concentrations for further risk assessment

Chemical	Concentration (µg/L)
Bromate	1.9E+2
Bromochloroacetic acid	7.0E+0
Bromochloroacetonitrile	1.1E+0
Chloral hydrate	8.3E+0
Chloropicrin	6.9E-1
Dalapon	2.4E+0
Dibromoacetic acid	6.9E+1
Dibromoacetonitrile	1.0E+1
Dibromochloroacetic acid	2.0E+1
Dibromochloromethane	2.5E+1
Dichloroacetic acid	5.8E+0

Chemical	Concentration (µg/L)
Dichloroacetonitrile	6.9E+0
Dichlorobromoacetic acid	2.5E+1
Dichlorobromomethane	1.8E+1
1,2-Dichloropropane	2.1E+0
Monobromoacetonitrile	2.4E+0
Tribromoacetic acid	2.6E+2
Tribromoacetonitrile	1.1E+1
Tribromomethane	3.8E+2
Trichloroacetic acid	4.5E+1
Trichloromethane	2.6E+1

4 RESPONSE TO THE GESAMP-BWWG REQUESTS

4.1 The Group recalled that it had already provided the following recommendations during its evaluation of the application for Basic Approval of the system (see document MEPC 64/2/6, annex 5), and the applicant had provided the following responses in their Final Approval dossier (see table 5).

Table 5: Applicant's responses to recommendations made by the Group during evaluation for Basic Approval

Section in MEPC 64/2/6, annex 5	Group's Recommendation	Applicant's response	Group's reaction
7.4.2	The Group recognized that as this BWMS is based on direct electrolysis of the uptake water, there will be a lower limit of uptake water PSU when the system becomes ineffective and noted that the applicant is to undertake further tests to determine PSU and temperature limits for the system. The Group recommended that the result of this additional testing is provided for the Final Approval assessment.	<ul style="list-style-type: none"> - Land-based test of the MARINOMATE™ BWMS was conducted on seawater (> 32 PSU) and brackish water (20-22 PSU). - The limitation tests were carried out on low salinity (8 PSU) and low temperature (4°C). - Low salinity test: biological efficacy, chemical analysis and ecotoxicity test → satisfied with the Guidelines (G8) and Procedure (G9). - Low temperature test: verifying the performance of the electrolyser unit (Average maximum allowable dosage of Active Substance: 10.18 mg/L TRO as Cl₂). 	<i>The Group was satisfied with the response</i>
7.4.3	The Group noted that the applicant intends to develop a cleaning system to maintain the cleanliness of the plankill pipe™ unit during operation. The Group recommended that this cleaning operation is fully detailed in the operating	<ul style="list-style-type: none"> - Aquatic organisms in the ballast water can compose biofilms and proliferate by living and multiplying in the wall of the plankill pipe™ unit. - Formation of biofilms: can reduce flow rate, increase the pressure → Adapted circulation system in order to inhibit the formation of biofilms inside of the plankill pipe™ unit. - Composition of circulation system: circulation pump, flow meter, valves 	<i>The Group noted the response</i>

	manual to be supplied for Final Approval.	<ul style="list-style-type: none"> - Function of circulation system: transfer Active Substance (10 mg/L TRO as Cl_2) generated by electrolyser unit into the front of the plankill pipe™ unit. - Set up TRO concentration of mixing point (in front of plankill pipe™ unit): 0.5 mg/L TRO as Cl_2. → Present in most disinfected drinking water at concentration of 0.2 - 1.0 mg/L chlorine (Guidelines for drinking water quality, 4th edition (2011), WHO). - Circulation flow rate for 0.5 mg/L TRO as Cl_2 at mixing point: 14 m³/hr (about 5% of ballast inlet water). - Chemical analysis result of worse condition (28 m³/hr, 1.0 mg/L TRO as Cl_2). - Not expected to increase significantly in by-products generated between circulation and non-circulation. - Pressure changes in front and rear of the plankill pipe™ unit did not happen during the land-based test. 	
7.4.4	The Group noted that the applicant intends to develop a flushing function to counter fouling of the electrolyser unit and also to perform long term performance testing. The Group recommended that for any cleaning system to be employed the results of the long-term performance testing is fully detailed in the application for Final Approval.	<ul style="list-style-type: none"> - A variety of cations (Mg^{2+}, Ca^{2+}, etc.) in the ballast water generate insoluble sediments, such as $\text{Ca}(\text{OH})_2$, $\text{Mg}(\text{OH})_2$, MgO, CaCO_3. - Fouling or scale formation: reduction of the electrolyser unit efficacy, increasing of the rectifier power supply, but some of scales are detached by strong velocity of inlet water because the electrolyser unit of MARINOMATE™ BWMS is installed directly in the main ballast pipe line. - As a result of the land-based test (six months), current amount was not much changed from average 2760 A (min.) - 2857 A (max.) in seawater to average 3108 A (min.) - 3272 A (max.) in brackish water. → No effect on fouling. - Replacement of an electrode module is recommended for the efficiency of the electrolyser unit according to long-term operating. → Details of replacement of the electrode module are described in appendix 8. 	<i>The Group noted the response</i>

7.4.5	The Group recommended that it is ensured that the control system can maintain the maximum allowable dose of 10 mg/L TRO as Cl ₂ at all times and that this is verified in the application for Final Approval.	<ul style="list-style-type: none"> - The maximum allowable dose of Active Substance: 10 mg/L TRO as Cl₂. - System control unit is linked to flow rate, conductivity meter and rectifier and has a feed-back system to maintain the target TRO concentration. - Operating control logic is set for the feed-back system (PID control) - During ballasting, TRO concentrations as a maximum dosage of system was 10 ± 0.58 mg/L TRO as Cl₂. 	<i>The Group noted the response</i>
7.4.6	The Group recommended that appropriate data for the neutralization function is provided to ensure the MADC is maintained at all times to avoid unacceptable TRO levels in particular at the beginning of the discharge.	<ul style="list-style-type: none"> - The Maximum Allowable Discharge Concentration (MADC): 0.2 mg/L TRO as Cl₂. - Neutralizing agent: aqueous solution of sodium thiosulfate (25%). → Aqueous solution type is possible to inject neutralizing agent as the same concentration. - Using two TRO sensors: before and after neutralization. - The dosing rate of neutralizing agent is controlled depending on the discharge flow rates and residual TRO concentration in the ballast tank. - By overdose of the neutralizing agent at the beginning of deballasting, MADC was kept to 0.2 mg/L TRO as Cl₂ for the land-based test. 	<i>The Group was satisfied with the response</i>
7.4.7	The Group recommended that the degas function for full-scale application is fully detailed in the application for Final Approval.	<ul style="list-style-type: none"> - One of the by-products generated by electrochemical disinfection: hydrogen gas (H₂). - Property of hydrogen gas: colourless, odourless, nontoxic, high flammable - Installed a gas separation component for detecting concentration of hydrogen gas for land-based test. - After checking the amount of gas collection, conduct sampling. - Gas separation component, air vent, hydrogen gas detector will be composed for ventilation of the hydrogen gas at shipboard test and the details of each component are described in appendix 8. 	<i>The Group noted the response</i>
7.4.8	The Group recommended that all risk mitigation measures to be put in place related to the storage and loading of the sodium thiosulfate neutralizing chemical to the BWMS are fully detailed in the operating manual that is to be developed for this system.	<ul style="list-style-type: none"> - Neutralizing agent: aqueous solution of sodium thiosulfate (25% - order production). - Property of sodium thiosulfate: non-flammable, odourless, stable under normal temperature and pressure. - Transfer: manufacturing plant (special storage container) → by truck or other vehicles (barge) → designated port. - Loading: using ship's crane on deck - Filling: From the storage tank on deck to the neutralization tank located in an engine-room or pump-room using gravity. 	<i>The Group noted the response</i>

		<ul style="list-style-type: none"> - Working of the crew: at loading and connection/disconnection of flexible hose at filling. - Risk mitigation measures: wearing of PPE according to each step. 	
7.4.9	The Group recommended for the further ecotoxicity testing that appropriate QA/QC is followed, including assessment of the test water quality and analysis for Relevant Chemicals.	<ul style="list-style-type: none"> - Ecotoxicity tests for applying to Final Approval were performed under appropriate quality assurance and quality control (QA/QC). - For QA/QC of ecotoxicity testing, conducted reference toxicant tests with algae (ISO 10253) and rotifer (ASTM E 1440-91) before each test cycle. - The results of reference toxicant test were presented in appendix 6. - For assessment of the test water quality, conducted Pass/Fail tests (WET testing) and relevant chemical analysis with intake water to ensure that there was no toxic effect on aquatic organisms in test water and verified that intake water for land-based test was nontoxic. 	<i>The Group was satisfied with the response</i>
7.4.10	The Group also noted that the applicant had not provided information regarding the identification and description of the unit operations associated with this system. This information is considered by the Group to be essential to identify the exposure routes of concern for the crew and consequently to perform a realistic human health risk assessment. The Group recommended that this information be fully considered and taken into account for Final Approval.	<ul style="list-style-type: none"> - Realistic human health risk assessment was performed according to the Methodology in BWM.2/Circ.13/Rev.1. - Exposure assessment was carried out. - Ballast water sampling, periodic cleaning of ballast tank and ballast tank inspection for crew. - Also, risk assessment for the general public on situations in which might be exposed to treated ballast water during swimming and eating seafood were carried out. 	<i>The Group noted the response</i>
7.4.11	The Group recommended that the corrosion testing be conducted in accordance with the guidance provided in section 5.1 of the "Report of the eighth meeting of the GESAMP-BWWG", contained in MEPC 59/2/16 and that the results should be provided for Final Approval.	<ul style="list-style-type: none"> - The corrosion test was carried out for duration of six months in accordance with GESAMP-BWWG recommendations on corrosion testing (MEPC 59/2/16). - Corrosion test of coated material <ul style="list-style-type: none"> - There was no significant change of performance of corrosion resistance between the untreated and treated water. - The result of corrosion creep from scribe test is nearly similar between treated and untreated sample. 	<i>The Group was satisfied with the response</i>

		<ul style="list-style-type: none"> - Corrosion test of uncoated substrates <ul style="list-style-type: none"> - The result of tests (immersion and vapour corrosion test, crevice corrosion test, polarization test, FE-SEM surface test), it would be reasonable to conclude that corrosion behaviours of uncoated metallic specimens in the untreated and treated water are on the same level. - Corrosion test uncoated non-metal substrates (NBR, EPDM, VITON (FKM)) <ul style="list-style-type: none"> - The physical property of immersion test was nearly similar results between the untreated and treated water. - The treated water of the MARINOMATE™ BWMS will not increase the corrosion effect of the ballast tank and ballast pipelines. 	
7.4.12	The Group noted that the applicant is developing handling instructions and procedures for the use of the neutralizer chemical together with designing suitable containers for on-board use. The Group recommended that this procedure be fully detailed in the operating manual to be supplied for Final Approval, together with requirements for personal protective equipment (PPE) to be used during the neutralizer filling operation.	<p>Neutralizing agent: aqueous solution of sodium thiosulfate (25%).</p> <ul style="list-style-type: none"> - Procedures for the use of neutralizing agent: as mentioned in 1.1.8. - When refilling the neutralizing agent in the storage container to the neutralization tank located in an engine-room or pump-room, a flexible hose is used for transportation. - Working of ship's crew: connect/disconnection of flexible hose from the storage container to the neutralization tank. <p>→First of all, crew must be wearing personal protective equipment (PPE).</p> <ul style="list-style-type: none"> - The crews follow personal safety procedures and rules for all the operations carried on board ships. - If eye and skin contact occurs during operation, need to flush with plenty of water for at least 15 minutes. 	<i>The Group noted the response</i>
7.4.13	The Group recommended that future ecotoxicity testing on algae should be performed in accordance with OECD 201.	The validation of WET testing with algae, diatom was according not only to OECD 201 but also ISO 10253 whereby average growth rate in the control is more than 0.9 during the test periods, mCV of section-by-section specific growth rate in the control do not exceed 35%, CV of control specific growth rate does not 7%, and pH variation does not exceed 1.	<i>The Group was satisfied with the response</i>
7.4.14	The Group recommended that the presence of trichloroacetic acid is further quantified by the applicant for the Group's assessment in the Final Approval dossier.	<p>Trichloroacetic acid is detected in natural salt water.</p> <ul style="list-style-type: none"> - Generally brominated by-products are dominantly formed during electrolysis of salt water. - Test water on seawater: 8.49 µg/L (land-based test), 70.0 µg/L (lab-scale test) - Treated water on seawater: N.D. <ul style="list-style-type: none"> - 45.1 µg/L (land-based test), 	<i>The Group was satisfied with the response</i>

		<p>65.3 – 139 µg/L (lab-scale test)</p> <ul style="list-style-type: none"> - Test water on brackish water: 12.1 µg/L (land-based test), 0.83 µg/L (lab-scale test) - Treated water on brackish water: 28.9 µg/L (land-based test), 9.92 – 55.8 µg/L (lab-scale test) - Trichloroacetic acid was not present significant occurrence pattern according to salinity levels, water types and sampling time. <p>Moreover, trichloroacetic acid was detected in test water.</p>	
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4.2 During the GESAMP-BWWG meeting, the Group posed 12 questions to the applicant. The Group's questions (in **bold text**), the applicant's responses (in plain text) and the reactions of the Group (in *italic text*) are noted below, in numerical order of the individual questions.

Question 1

In section 7.4.1, table 41 of the non-confidential dossier a PNEC is mentioned for potassium bromate: 1.7E+6 mg/L. Please explain how this PNEC was derived as the Group was not able to identify this data in the dossier, especially because of the difference with sodium bromate. Also in document MEPC 65/INF.14, no ecotoxicity data were presented on potassium bromate.

Response 1

We fully agree with the Group's concern as pointed out that toxicity data for potassium bromate cannot be found in document MEPC 65/INF.14. We carefully tried to find the toxicity value, but we could not find it. Thus, we used the expected toxicity value using ECOSAR v1.11 to calculate the PNEC value as below:

Table: Predicted toxicity values of potassium bromate by ECOSAR v1.11

Organism	Duration	End-point	Predicted toxicity (mg/L)
Fish	96h	LC ₅₀	9.53E+07
Daphnia	48h	LC ₅₀	2.93E+07
Green algae	96h	EC ₅₀	1.74E+06

Group's reaction

The Group was satisfied with the response.

Question 2

Appendix 3 of the confidential dossier shows that the TRO concentration in the dose is above 10 mg/L, the recommended dose. The maximum found was 11.11 mg/L. The Group recalled that during the Basic Approval evaluation it was recommended to improve the dosing method. It seems that this improvement was not achieved. The Group also recognized that the monitored TRO fluctuated even after 10 minutes from operation starting. Please comment.

Response 2

The maximum TRO dosage of MARINOMATE™ BWMS is 10 mg/L, which has been sustained during ballasting at all times.

In the land-based test, however, 4 times (11.37(1st), 11.08(2nd), 11.12(5th), 11.11(11th)) of TRO fluctuations were found among the entire 12 times of operations.

Trying to find out this reason during land-based testing, we found out that there were air bubbles in a defective inlet tube, which interfered UV detection in the cell (cuvette) to increase TRO values as observed. Finally we replaced the inlet tube with a new one (1/4 inches in diameter) and then we rectified it. Accordingly, any problem was not found from 12th test cycles to the present.

In addition, we will ensure more concrete stability through undergoing shipboard testing before achieving governmental type approval.

Group's reaction

The Group noted the response.

Question 3

It is noted that, in section 3.1.3 of appendix 3, when ballasting at 250m³/h, there is a continual recirculation of treated water, rated at 14m³/h, back to the inlet of the plankill™ unit. Also the applicant describe that "Although some of treated water after passing through the electrolyser unit is circulated, it does not increase significantly the DBPs concentration between circulation and non-circulation". Please provide scientific explanation to support the observation above.

Response 3

(data deemed to be confidential and removed at the request of the submitting Administration)

Group's reaction

The Group noted the response.

Question 4

The Group requests clarification on the neutralizer delivery process. Section 5.2.3 of appendix 8 states that the neutralizer agent consists of a 25% aqueous solution of sodium thiosulfate. Please explain the function of the 120 L stock containers.

Response 4

KT Marine Co., Ltd. chose 25% aqueous solution of sodium thiosulfate as a neutralizing agent during deballasting. 120 L stock containers were supposed to be used for an emergency situation that would occur in the event of a lack of neutralizing agent during deballasting, but if the neutralizing agent is supplied sufficiently in a port, stock containers are not necessary. KT Marine decided to

exclude the 120 L stock container in order to ensure ship and crew safety. Therefore, the neutralizing agent of MARINOMATE™ BWMS will be supplied directly and sufficiently in a port.

Group's reaction

The Group was satisfied with the response.

Question 5

Page 34 of the operating manual refers to supplying the neutralizing agent to the neutralizing tank via a flexible hose. Please describe how this hose will run through the ship from the refill tank to the neutralization storage tank as shown in the diagram on page 36 of the manual.

Response 5

(data deemed to be confidential and removed at the request of the submitting Administration)

Group's reaction

The Group noted the response.

Question 6

Page 38 of appendix 8 states that, during deballasting, the neutralizer dosage, when in the manual mode, will be adjusted depending on the TRO concentration after neutralization. Please outline the actions that a crew member will have to take to effectively monitor and control the MADC of the Active Substance at all times during the ballast discharge procedure. According to the Group these actions should be outlined in the operating manual.

Response 6

We are sorry for incorrect description and explanation. The MARINOMATE™ BWMS should be operated automatically (refer to section 5.3, appendix 8) whenever ballasting and deballasting operation for ship and crew safety because manual operation may cause incident by operators' errors.

Group's reaction

The Group was satisfied with the response.

Question 7

Section 8.1.2 of the non-confidential dossier highlights system flooding controls. It is stated that a level gauge fitted to the neutralization tank will alarm if high or low level tank levels are detected and the dosage rates of the neutralizer will then be controlled automatically. Please explain the function of this alarm and how the dosage rate of the neutralizer is related to the tank level.

Response 7

A level sensor is set in the neutralization tank to prevent overflow caused by excessive injection when refilling neutralizing agent and to monitor water levels of the neutralization tank when injecting neutralizing agent during de ballasting. The neutralization tank varies depending on ship size and the ballast pump capacity and the high level is set to 90% of tank capacity, low level is 20% and low-low level is 10%. The dosage rate of the neutralizer is definitely not related to the tank level. The explanation of the relationship between level sensor and neutralizer dosage rates described in the Final Approval dossier (non-confidential, section 8.1.2) is not correct.

To clarify, KT Marine would like to delete "and dosage rates of the neutralizing agent are controlled automatically" in section 8.1.2.

Group's reaction

The Group noted the response.

Question 8

With reference to section 5.1.3. of appendix 8, please indicate how drying out of the electrolyser and rectifier units will be achieved.

Response 8

The MARINOMATE™ BWMS is mainly installed in an engine-room or in a pump-room. The atmosphere of a ship's engine-room and pump-room is generally dry. For your reference, the humidity test of the MARINOMATE™ BWMS was completed in the environmental test. Section 5.1.3 of appendix 8 was supposed to describe details of the installation place and meant to avoid humid sites for installing. Regretfully it was described in that way. In fact, there is no way for the electrolyser unit and the rectifier unit to be moisturized as they have a cover. Of course, it could be dried up with a towel when turned off.

Group's reaction

The Group noted the response.

Question 9

In its evaluation of the Basic Approval application of this system, the Group asked the applicant to specify the lower salinity limit of uptake water, in which the system can be operated effectively and safely. For the Final Approval application, the applicant performed additional tests on efficacy, toxicity and by-product formation in water of a salinity of 8 PSU. However, neither the application dossier nor the operating manual specifies a minimum salinity requirement for the operation of the system. Therefore, the Group asks the applicant:

- .1 to clarify if 8 PSU is considered the lower salinity limit for effective and safe operation of the system; and**

- .2 to specify how the system operator will be informed, if the intake water does not meet the minimum salinity requirement.**

Response 9

At 8 PSU, low salinity test was conducted to verify limiting conditions for operation of the MARINOMATE™ BWMS (refer to appendix 9, Final Approval). The test was carried out in accordance with Guidelines (G8) and chemical analysis, WET testing and operation records are monitored. As a result of the test, an allowable salinity for operation of the MARINOMATE™ BWMS is 8 PSU, at which the TRO dosage was in average 9.67mg/L. Therefore, KT Marine guarantees operation of the MARINOMATE™ BWMS at the lowest salinity (above 8 PSU) and operation at salinity below 8 PSU is not allowed. This will be described in the operation manual and added in the system control logic, such as an attached file. In addition, this condition will be communicated to the buyer clearly.

(data deemed to be confidential and removed at the request of the submitting Administration)

Figure 1: Operation logic of low salinity control

Group's reaction

The Group was satisfied with the response.

Question 10

The Group noted that toxicity was found in algae, crustacean and fish toxicity tests. The lowest NOECs were 6.25%, 12.5% and 50% for algae, crustacean and fish WET tests, respectively. Was there any review of this toxicity data in an effects assessment evaluation (paragraph 6.2.4 in the Methodology)?

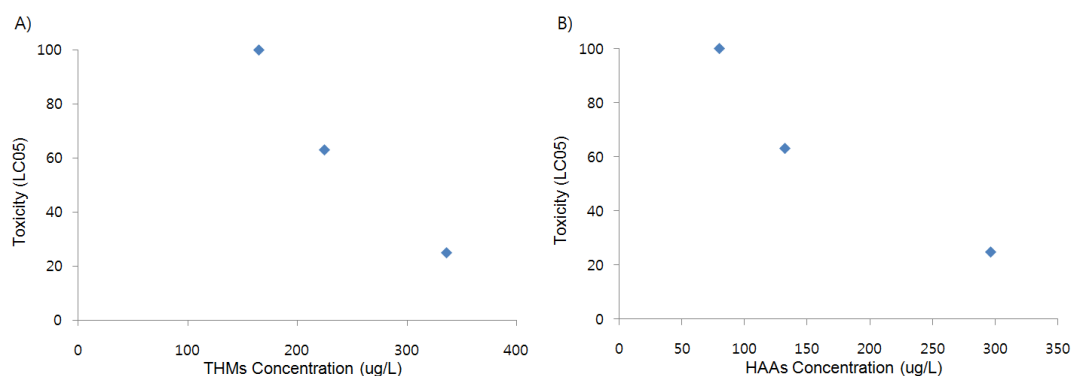
Response 10

As pointed out by the Group, the WET test had been performed with discharge water after 5 days holding from the MARINOMATE™ BWMS according to section 6.2.4 in the revised Methodology. Regarding further review of the observed toxicities, we cannot find sufficient information to fully understand such toxicities and its origins.

We carefully reviewed the relationship between the toxicity and test water quality in the discharge water. In particular, the highest amounts of disinfection by-products (THMs and HAAs) were observed in the treated water of > 32 PSU test among the three salinities test cycles. We found the toxicity profile which gradually decreased with decreasing salinity.

PBT evaluation for THMs and HAAs shows that there is no potential toxicity. The PEC/PNEC results were below 1 in general harbour (section 7.4.2 of non-confidential dossier). Therefore, we cannot find the relationship between the toxicity and DBPs. In addition, we carried out statistical analyses to figure out the correlation between DBPs and toxicity. In invertebrates, there seems to exist apparent negative correlation between THMs and LC₅, HAAs and EC₅, respectively. We are sorry that we were unable to calculate statistical confidence levels because

of lack of enough replicate data and number of tests in which toxicities were detected. Comparing toxicity results with the Basic Approval application, toxicity values in the Final Approval application was higher than in the Basic Approval application. We are not sure, but this result might have been derived from different test water sources as we used Busan seawater for Basic Approval and Geoje seawater for Final Approval testing, respectively. Even so, we do not exclude other possibilities for the toxicities to result from unidentified factors. We will keep an eye on this matter to protect the aquatic environment.



Correlation between EC₅ and THMs (A) and HAAs (B) concentration in invertebrates

Group's reaction

The Group noted the response.

Question 11

The Group noted that the RCRs based on the DMEL values were not calculated by the applicant for the occupational scenarios. The Group has identified the scenario of "periodic cleaning of ballast tanks" as the worst-case scenario in terms of occupational risk. For this scenario, all the RCR estimated based on the DMEL values are above 1 with exception of one substance – dichloroacetic acid. As this operation is likely to occur on the long-term, this risk has to be mitigated by implementing operational conditions and use of PPE, to avoid exposure. Please consider that DMEL means Derived Minimal Effect Level and not Derived Maximum Exposure Level (page 40, non-confidential dossier), therefore exposure should be avoided at all terms.

Response 11

We apologize that we did not calculate the RCRs based on the DMEL and appreciate Group's efforts for calculating. In the scenario of "periodic cleaning of ballast tanks", we decided to evaluate the exposure in accordance with operation involving the crew and/or port State workers in the Methodology (BWM.2/Circ.13/Rev.1) and calculated the DNELs for acute/short exposure. As pointed out by the Group, we agree that there would be potential risks by inhalation and dermal exposure during periodic cleaning of ballast tanks on long-term (more than 8 hr day). Thus, to prevent unacceptable risks to the worker, appropriate procedures for tank entry will be developed (i.e. full ventilation of a

ballast tank prior to worker entry, continuous ventilation during tank entry, wearing PPE for respiratory protection, skin and eye protection).

Group's reaction

The Group was satisfied with the response.

Question 12

The Group noted that the applicant used the same test species, *Skeletonema costatum*, in the WET for all fresh, brackish and seawater. The Group also noted that the applicant added 'seawater salts' to the test media to adjust the salinity from 8.0 PSU to that for *S. costatum*. Please clarify what is the salinity after adding the 'seawater salts' for WET testing using ballast water at 8 PSU. Also, clarify the components of the 'seawater salts'.

Response 12

It is regrettable that we planned to add seawater salts prior to undertaking WET test in the planning phase, if test water salinity was not satisfied 8 PSU. With this salinity adjustment we also planned to perform preliminary tests to evaluate the negative effects to test organisms by adding seawater salts simultaneously. However, salinity adjustment was not required for carrying out WET testing since the salinity of test water was 8 PSU which sampled from discharging treated and control water after 5 days holding time (please refer to appendix 6, section 3.1.2). Accordingly, we did not use seawater salt to conduct WET test as described in the test plan. Anyhow we are sorry to make you confused.

Group's reaction

The Group noted the response.

5 HAZARD PROFILE AND EXPOSURE DATA FOR RELEVANT CHEMICALS

5.1 Predicted No Effect Concentrations (PNEC)

5.1.1 The Group has defined the Relevant Chemicals for which a further risk assessment has to be carried out (see table 4). The Group has used the data available in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water for all substances except tribromoacetonitrile where the data provided by the applicant had been used. The PNECs of the Relevant Chemicals are shown in table 6.

Table 6: PNEC values of Relevant Chemicals

Relevant Chemicals	Harbour			Near sea		
	AF	PNEC (µg/L)	Rule No.	AF	PNEC (µg/L)	Rule No.
Bromate		1.3E+0			1.3E+1	
Bromochloroacetic acid		1.6E+1			1.6E+1	
Bromochloroacetonitrile		6.9E-1			6.9E+0	
Chloral hydrate		9.7E+1			9.7E+2	
Chloropicrin		2.5E-2			2.5E-2	
Dalapon		1.1E+1			1.1E+2	
Dibromoacetic acid		6.9E+0			6.9E+1	
Dibromoacetonitrile		5.5E-2			5.5E-1	

Relevant Chemicals	Harbour			Near sea		
	AF	PNEC (µg/L)	Rule No.	AF	PNEC (µg/L)	Rule No.
Dibromochloroacetic acid		6.0E+1			6.0E+1	
Dibromochloromethane		6.3E+0			2.7E+2	
Dichloroacetic acid		2.3E+0			2.3E+1	
Dichloroacetonitrile		2.4E+1			2.4E+2	
Dichlorobromoacetic acid		6.0E+1			6.0E+1	
Dichlorobromomethane		7.8E+1			7.8E+1	
1,2-Dichloropropane		4.1E+2			4.1E+2	
Monobromoacetonitrile		2.3E+1			2.3E+2	
Sodium thiosulphate		8.1E+2			8.1E+2	
Tribromoacetic acid		6.0E+1			6.0E+1	
Tribromoacetonitrile*	10000	2.3E-1	1	1000	2.3E+0	1
Tribromomethane		9.6E+1			2.9E+2	
Trichloroacetic acid		6.0E+1			6.0E+1	
Trichloromethane		1.5E+2			1.5E+2	

* Values from the applicant are being used.

5.2 Derived No Effect Levels (DNEL) and/or Derived Minimum Effect Level (DMEL)

5.2.1 The Group noted the CMR properties associated with the selected Relevant Chemicals (see table 4) and the DNEL values to be used in the human risk assessment (see table 7).

Table 7: CMR properties for selected Relevant Chemicals

	Carcinogenic	Mutagenic	Reprotoxicity	CMR
Bromate	1	0	0	1
Bromochloroacetic acid	1	0	1	1
Bromochloroacetonitrile	0	0	0	0
Chloral hydrate	0	0	0	0
Chloropicrin	0	0	0	0
Dalapon	0	0	0	0
Dibromoacetic acid	1	1	0	1
Dibromoacetonitrile	0	0	0	0
Dibromochloroacetic acid	0	0	0	0
Dibromochloromethane	1	0	0	1
Dichloroacetic acid	1	0	0	1
Dichloroacetonitrile	0	0	0	0
Dichlorobromoacetic acid	0	0	0	0
Dichlorobromomethane	1	0	0	1
1,2-Dichloropropane	0	0	0	0
Monobromoacetonitrile	0	0	0	0
Tribromoacetic acid	0	0	0	0
Tribromoacetonitrile	0	0	0	0
Tribromomethane	1	0	0	1
Trichloroacetic acid	0	0	0	0
Trichloromethane	0	0	1	1

5.2.2 Based on these results, the Group concluded that some chemicals are CMR substances.

Table 8: DNELs and DMELs to be used in the risk assessment for humans

Chemical	DNEL (mg/kg bw/d) Crew	DNEL (µg/kg bw/d) General public	DMEL (µg/kg bw/d)
Bromate	2.2E-2	1.1E+1	1.1E-4
Bromochloroacetic acid	1.3E+0	6.3E+2	N.D.
Bromochloroacetonitrile	1.5E-1	7.5E+1	NA
Chloral hydrate	6.7E-1	3.3E+2	NA
Chloropicrin	2.0E-3	1.0E+0	NA
Dalapon	1.7E-1	8.4E+1	NA
Dibromoacetic acid	7.2E-2	3.6E+1	1.3E-4
Dibromoacetonitrile	1.6E-1	8.2E+1	NA
Dibromochloroacetic acid	3.0E-1	1.5E+2	NA
Dibromochloromethane	2.1E-1	1.1E+2	1.5E-3
Dichloroacetic acid	1.2E-1	6.0E+1	1.7E-3
Dichloroacetonitrile	5.7E-2	2.9E+1	NA
Dichlorobromoacetic acid	8.6E-1	4.3E+2	NA
Dichlorobromomethane	4.0E-2	2.0E+1	2.4E-3
1,2-Dichloropropane	8.9E-1	4.4E+2	NA
Monobromoacetonitrile	8.0E-3	4.0E+0	NA
Tribromoacetic acid	8.6E-1	4.3E+2	NA
Tribromoacetonitrile*	3.3E-3	1.7E+0	NA
Tribromomethane	1.8E-1	9.0E+1	7.7E-3
Trichloroacetic acid	8.6E-1	4.3E+2	NA
Trichloromethane	5.3E-2	2.6E+1	NA

* Values from the applicant are being used.

NA: not available.

N.D.: Not detected.

5.3 Predicted Environmental Concentrations (PEC)

5.3.1 The Group estimated the predicted environmental concentrations (PEC) of chemicals using the Marine Anti-foulant Model to Predict Environmental Concentrations (MAMPEC version 3.0 with the GESAMP-BWWG emission scenario). For the calculation of the PEC, the concentrations mentioned in table 4 in section 3 were used to establish the PEC in the harbour and in the near sea situation. The results are shown in table 9.

Table 9: PEC from MAMPEC modelling results from the GESAMP-BWWG Model Harbour for the harbour and the near sea scenario

Chemical name	PEC (µg/L)	
	Harbour	Near sea
Bromate	5.1E+0	4.1E+1
Bromochloroacetic acid	1.9E-1	1.5E+0
Bromochloroacetonitrile	1.4E-2	2.3E-1
Chloral hydrate	2.2E-1	1.8E+0
Chloropicrin	6.8E-3	1.4E-1
Dalapon	6.5E-2	5.1E-1
Dibromoacetic acid	1.9E+0	1.5E+1
Dibromoacetonitrile	2.7E-1	2.1E+0
Dibromochloroacetic acid	5.4E-1	4.2E+0
Dibromochloromethane	2.3E-1	5.1E+0

Chemical name	PEC (µg/L)	
	Harbour	Near sea
Dichloroacetic acid	1.6E-1	1.2E+0
Dichloroacetonitrile	1.8E-1	1.5E+0
Dichlorobromoacetic acid	6.7E-1	5.3E+0
Dichlorobromomethane	1.4E-1	3.7E+0
1,2-Dichloropropane	1.4E-2	4.3E-1
Monobromoacetonitrile	6.5E-2	5.3E-1
Sodium thiosulphate	1.0E+2	8.1E+2
Tribromoacetic acid	7.0E+0	5.5E+1
Tribromoacetonitrile*	3.0E-1	1.2E+0
Tribromomethane	4.1E+0	7.8E+1
Trichloroacetic acid	1.2E+0	9.5E+0
Trichloromethane	1.8E-1	5.3E+0

* Values from the applicant are being used.

5.4 Concentration of Relevant Chemicals in the atmosphere

5.4.1 Once the concentrations of chemicals in the ballast tank and after discharge, that is the predicted environmental concentration (PEC) values as calculated by MAMPEC, have been established, the corresponding concentration of the chemicals evaporating into the air may be calculated (see table 10).

Table 10: Resulting concentrations to be used in the risk assessment for humans

Chemical	Crew		General public	
	Concentration in tank (µg/L)	Concentration in air (mg/m ³)	Concentration MAMPEC (µg/L)	Concentration in air (mg/m ³)
Bromate	1.9E+2	7.7E-5	5.1E+0	2.1E-7
Bromochloroacetic acid	7.0E+0	4.5E-7	1.9E-1	1.2E-9
Bromochloroacetonitrile	1.1E+0	5.8E-6	1.4E-1	7.1E-8
Chloral hydrate	8.3E+0	9.9E-7	2.2E-1	2.6E-10
Chloropicrin	6.9E-1	1.2E-3	6.8E-3	1.2E-6
Dalapon	2.4E+0	6.3E-7	6.5E-2	1.7E-9
Dibromoacetic acid	6.9E+1	1.2E-6	1.9E+0	3.4E-9
Dibromoacetonitrile	9.6E+0	1.6E-5	2.6E-1	4.4E-8
Dibromochloroacetic acid	2.0E+1	2.0E-7	5.3E-1	5.6E-10
Dibromochloromethane	2.5E+1	1.0E-1	2.3E-1	9.3E-5
Dichloroacetic acid	5.8E+0	2.0E-7	1.6E-1	5.5E-10
Dichloroacetonitrile	6.9E+0	6.5E-1	1.8E-1	2.8E-7
Dichlorobromoacetic acid	2.5E+1	8.1E-7	6.7E-1	2.2E-9
Dichlorobromomethane	1.8E+1	1.6E-1	1.4E-1	1.2E-4
1,2-Dichloropropane	2.1E+0	2.4E-2	1.4E-2	1.6E-5
Monobromoacetonitrile	2.4E+0	3.5E-5	6.3E-2	9.1E-8
Tribromoacetic acid	2.6E+2	3.5E-6	6.9E+0	9.5E-9
Tribromoacetonitrile	1.1E+1	2.1E-7	3.0E-1	5.7E-10
Tribromomethane	3.8E+2	8.4E-1	4.1E+0	9.0E-4
Trichloroacetic acid	4.5E+1	3.0E-6	1.2E+0	8.1E-9
Trichloromethane	2.6E+1	3.9E-1	1.8E-1	2.7E-4

6 WET TESTS

6.1 The Group noted that the results of WET tests on algae, crustacean and fish performed by the applicant with 100% treated ballast water after neutralization for seawater (33 PSU), brackish water (21 PSU) and water at the limiting salinity for normal operation of the BWMS (8 PSU) were presented.

6.2 The Group noted that the results of the WET tests were summarized in table 11.

Table 11: Summary of WET tests of treated ballast water after neutralization to test organisms

Test	Test organism	Salinity (PSU)	End points (%)		References/ guidelines
			NOEC	L(E)C ₅₀	
Algal growth inhibition	<i>Skeletonema costatum</i>	33	6.25	82.74	OECD 201 (2011)
		21	12.5	>100	
		8	12.5	>100	
Acute crustacean	<i>Brachionus plicatilis</i>	33	100	>100	ASTM E1440-91
		21	100	>100	
		8	100	>100	
Acute fish	<i>Paralichthys olivaceus</i>	33	100	>100	OECD 203
		21	100	>100	
	<i>Cyprinodon variegatus</i>	8	100	>100	US EPA 821-R-02-012
Chronic crustacean	<i>Brachionus plicatilis</i>	33	12.5	>100	ASTM E1440-91 - Janssen et al.,1994
		21	50	>100	
		8	100	>100	
Chronic fish	<i>Paralichthys olivaceus</i>	33	50	>100	OECD 212
		21	100	>100	
	<i>Cyprinodon variegatus</i>	8	100	>100	US EPA 821-R-02-012

6.3 The Group noted that there was a slight residual toxicity observed in growth inhibition tests of microalgae and also in the two chronic tests.

6.4 Although the Group is of the opinion that the observed toxicity in these tests would not have significant effects to the environment based on the experience with the evaluation of other similar electrolysis systems, the Group recommended that the residual toxicity should be verified to the satisfaction of the Administration prior to the issuance of the Type Approval Certificate.

7 RISKS TO SHIP SAFETY

7.1 The Group noted that during Basic Approval the potential risks of hydrogen gas were identified and it was recommended that the degas function for full-scale application be fully detailed. The Group noted that the applicant had installed a gas separator for this purpose. The Group recommended that particular care is required when considering the position of ventilation arrangements carrying this gas safely to atmosphere.

7.2 The Group noted that specific countermeasures that can be employed in this BWMS to deal with envisaged emergency and safety problems during the ballast water treatment have been summarized above. In particular, a summary of the various safety measures developed by the applicant is given above in section 2. The Group recognized that the operating manual presented was not sufficiently detailed and therefore recommended that the operating manual should be updated to include all the information necessary for the crew to operate this BWMS prior to the issuance of a Type Approval Certificate by the Administration.

7.3 The Group noted that a full report of corrosion tests had been included in the application for Final Approval and that no enhanced corrosion had been detected.

8 RISKS TO THE CREW

8.1 The Group noted that the applicant had performed the human risk assessment in accordance with the Methodology for information gathering and conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.1).

8.2 The Group made a risk assessment, taking into account the following scenarios from the Methodology in this case:

- .1 delivery, loading, mixing or adding chemicals to the BWMS;
- .2 ballast water sampling;
- .3 periodic cleaning of ballast tanks;
- .4 ballast tank inspections, and
- .5 normal work on deck unrelated to any of the above.

Delivery, loading, mixing or adding chemicals to the BWMS

8.3 The Group noted that a flexible hose is proposed to be used for refilling the neutralizer tank.

8.4 The Group recognized that this scenario is not covered by the standard scenario defined in the Methodology. Therefore, the Group recommended that the transfer of the neutralizer from the refill tank to the storage tank arrangements should consist of a fixed piping network acceptable to the Administration issuing type approval.

Ballast water sampling

8.5 The Group noted that the resulting dose from the aggregated exposure from ballast water sampling, when compared with a DNEL value, does not lead to a RCR above 1 for any substance (see table 12).

Table 12: Port State control, scenario: ballast water sampling (2 hours)

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	2.7E-5	3.3E-6	3.0E-5	2.2E-2	1.4E-3
Bromochloroacetic acid	9.8E-7	1.9E-8	1.0E-6	1.3E+0	8.0E-7
Bromochloroacetonitrile	1.5E-7	2.4E-7	4.0E-7	1.5E-1	2.6E-6
Chloral hydrate	1.2E-6	4.3E-9	1.2E-3	6.7E-1	1.7E-6
Chloropicrin	9.7E-8	5.3E-5	5.3E-5	2.0E-3	2.6E-2
Dalapon	3.4E-7	2.7E-8	3.6E-7	1.7E-1	2.1E-6
Dibromoacetic acid	9.6E-6	5.2E-8	9.7E-6	7.2E-2	13E-4
Dibromoacetonitrile	1.3E-6	6.6E-7	2.0E-6	1.6E-1	1.2E-5
Dibromochloroacetic acid	2.7E-6	8.5E-9	2.7E-6	3.0E-1	9.1E-6
Dibromochloromethane	3.5E-6	4.4E-3	4.4E-3	2.1E-1	2.0E-2
Dichloroacetic acid	8.1E-7	8.6E-9	8.2E-7	1.2E-1	6.9E-6
Dichloroacetonitrile	9.7E-7	4.6E-6	5.6E-6	5.7E-2	9.8E-5
Dichlorobromoacetic acid	3.5E-6	3.5E-8	3.5E-6	8.6E-1	4.1E-6
Dichlorobromomethane	2.5E-6	6.7E-3	6.7E-3	4.0E-2	1.7E-1
1,2-Dichloropropane	2.9E-7	1.0E-3	1.0E-3	8.9E-1	1.2E-3
Monobromoacetonitrile	3.4E-7	1.4E-6	1.8E-6	8.0E-3	2.2E-4
Tribromoacetic acid	3.6E-5	1.5E-7	3.6E-5	8.6E-1	4.2E-5
Tribromoacetonitrile*	1.5E-6	8.7E-9	1.6E-6	3.3E-3	4.7E-4
Tribromomethane	5.4E-5	3.5E-2	3.5E-2	1.8E-1	2.0E-1
Trichloroacetic acid	6.3E-6	1.3E-7	6.4E-6	8.6E-1	7.5E-6
Trichloromethane	3.6E-6	1.7E-2	1.7E-2	5.3E-2	3.2E-1

* Values from the applicant are being used.

8.6 For the DNEL evaluation, the Group concluded that as the RCR was below 1 for all substances, the ballast water sampling does not pose an unacceptable short-term risk to the port State control officers performing sampling.

8.7 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for dibromochloromethane, dichlorobromomethane and tribromomethane (see table 13).

Table 13: Port State control, scenario: ballast water sampling – DMEL approach

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	2.7E-5	3.3E-6	3.0E-5	1.1E-4	2.7E-1
Dibromoacetic acid	9.6E-6	5.2E-8	9.7E-6	1.3E-4	7.4E-2
Dibromochloromethane	3.5E-6	4.4E-3	4.4E-3	1.5E-3	2.9E+0
Dichloroacetic acid	8.1E-7	8.6E-9	8.2E-7	1.7E-3	4.8E-4
Dichlorobromomethane	2.5E-6	6.7E-3	6.7E-3	2.4E-3	2.8E+0
Tribromomethane	5.4E-5	3.5E-2	3.5E-2	7.7E-3	4.6E+0

8.8 The Group noted that the largest contribution to the aggregated exposure arises from the inhalation of vapours.

8.9 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast water sampling to prevent unacceptable long-term risks to the port State control officers performing sampling.

Periodic cleaning of ballast tanks

8.10 The Group noted that the resulting dose from the aggregated exposure from ballast tank cleaning, when compared with a DNEL value, leads to an RCR above 1 for trichloromethane (see table 14).

Table 14: Crew, scenario: ballast tank cleaning (8 hours)

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	6.2E-4	1.3E-5	6.3E-4	2.2E-2	2.9E-2
Bromochloroacetic acid	2.3E-5	7.5E-8	2.3E-5	1.3E+0	1.8E-5
Bromochloroacetonitrile	3.6E-6	9.6E-7	4.5E-6	1.5E-1	3.0E-5
Chloral hydrate	2.7E-5	1.7E-8	2.7E-5	6.7E-1	4.0E-5
Chloropicrin	2.2E-6	2.1E-4	2.1E-4	2.0E-3	1.0E-1
Dalapon	7.8E-6	1.1E-7	7.9E-6	1.7E-1	4.7E-5
Dibromoacetic acid	2.2E-4	2.1E-7	2.2E-4	7.2E-2	3.1E-3
Dibromoacetonitrile	3.1E-5	2.6E-6	3.4E-5	1.6E-1	2.1E-4
Dibromochloroacetic acid	6.3E-5	3.4E-8	6.3E-5	3.0E-1	2.1E-4
Dibromochloromethane	8.1E-5	1.7E-2	1.8E-2	2.1E-1	8.2E-2
Dichloroacetic acid	1.9E-5	3.4E-8	1.9E-5	1.2E-1	1.6E-4
Dichloroacetonitrile	2.2E-5	1.8E-5	4.1E-5	5.7E-2	7.1E-4
Dichlorobromoacetic acid	8.1E-5	1.4E-7	8.1E-5	8.6E-1	9.4E-5
Dichlorobromomethane	5.8E-5	2.7E-2	2.7E-2	4.0E-2	6.7E-1
1,2-Dichloropropane	6.8E-6	4.2E-3	4.2E-3	8.9E-1	4.7E-3
Monobromoacetonitrile	7.8E-6	5.8E-6	1.4E-5	8.0E-3	1.7E-3
Tribromoacetic acid	8.3E-4	5.9E-7	8.3E-4	8.6E-1	9.7E-4
Tribromoacetonitrile*	3.6E-5	3.5E-8	3.6E-5	3.3E-3	1.1E-2
Tribromomethane	1.2E-3	1.4E-1	1.4E-1	1.8E-1	7.8E-1
Trichloroacetic acid	1.5E-4	5.1E-7	1.5E-4	8.6E-1	1.7E-4
Trichloromethane	8.4E-5	6.6E-2	6.7E-2	5.5E-2	1.3E+0

* Values from the applicant are being used.

8.11 The Group noted that the largest contribution to the aggregated exposure was from inhalation. Therefore, the Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast tank cleaning to prevent unacceptable long-term risks to the crew performing tank cleaning.

8.12 The Group calculated the indicative RCR regarding potential cancer risk as detailed above and noted that the RCR was above 1 for all substances with a DMEL except dichloroacetic acid (see table 15).

Table 15: Crew, scenario: ballast tank cleaning – DMEL approach

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	6.2E-4	1.3E-5	6.3E-4	1.1E-4	5.7E+0
Dibromoacetic acid	2.2E-4	2.1E-7	2.2E-4	1.3E-4	1.7E+0
Dibromochloromethane	8.1E-5	1.7E-2	1.8E-2	1.5E-3	1.2E+1
Dichloroacetic acid	1.9E-5	3.4E-8	1.9E-5	1.7E-3	1.1E-2
Dichlorobromomethane	5.8E-5	2.7E-2	2.7E-2	2.4E-3	1.1E+1
Tribromomethane	1.2E-3	1.4E-1	1.4E-1	7.7E-3	1.8E+1

8.13 The Group recognized that the scenario "periodic cleaning of ballast tanks" is the worst-case scenario representing a potential risk to the crew by inhalation and dermal exposure. As this operation is likely to occur on a long-term basis, risk has to be mitigated by implementing operational conditions and using adequate RPE/PPE to reduce exposure as technically achievable.

8.14 The Group recommended that appropriate procedures be developed for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of a full ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of a ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;
- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.

Ballast tank inspection

8.15 The Group noted that the resulting dose from the exposure from ballast tank inspection, when compared with a DNEL value, does not lead to an RCR above 1 (see table 16).

Table 16: Crew, scenario: ballast tank inspection (3 hours)

Chemical	Scenario "inspection" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	5.0E-6	2.2E-2	2.3E-4
Bromochloroacetic acid	2.8E-8	1.3E+0	2.3E-8
Bromochloroacetonitrile	3.6E-7	1.5E-1	2.4E-6
Chloral hydrate	6.4E-9	6.7E-1	9.6E-9
Chloropicrin	7.9E-5	2.0E-3	3.9E-2
Dalapon	4.1E-8	1.7E-1	2.4E-7
Dibromoacetic acid	7.8E-8	7.2E-2	1.1E-6
Dibromoacetonitrile	9.9E-7	1.6E-1	6.2E-6
Dibromochloroacetic acid	1.3E-8	3.0E-1	4.3E-8
Dibromochloromethane	6.5E-3	2.1E-1	3.1E-2
Dichloroacetic acid	1.3E-8	1.2E-1	1.1E-7
Dichloroacetonitrile	6.9E-6	5.7E-2	1.2E-4

Chemical	Scenario "inspection" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Dichlorobromoacetic acid	5.2E-8	8.6E-1	6.1E-8
Dichlorobromomethane	1.0E-2	4.0E-2	2.5E-2
1,2-Dichloropropane	1.6E-3	8.9E-1	1.8E-3
Monobromoacetonitrile	2.2E-6	8.0E-3	2.7E-4
Tribromoacetic acid	2.2E-7	8.6E-1	2.6E-7
Tribromoacetonitrile*	1.3E-8	3.3E-3	4.0E-6
Tribromomethane	5.2E-2	1.8E-1	2.9E-1
Trichloroacetic acid	1.9E-7	8.6E-1	2.2E-7
Trichloromethane	2.5E-2	5.5E-2	4.7E-1

* Values from the applicant are being used.

8.16 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, ballast tank inspection does not pose an unacceptable short-term risk to the crew performing inspection.

8.17 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for dibromochloromethane, dichlorobromomethane, and tribromomethane (see table 17).

Table 17: Crew, scenario: ballast tank inspection – DMEL approach

Chemical	Scenario "inspection" (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	5.0E-6	1.1E-4	4.5E-2
Dibromoacetic acid	7.8E-8	1.3E-4	6.0E-4
Dibromochloromethane	6.5E-3	1.5E-3	4.4E+0
Dichloroacetic acid	1.3E-8	1.7E-3	7.6E-6
Dichlorobromomethane	1.0E-2	2.4E-3	4.2E+0
Tribromomethane	5.2E-2	7.7E-3	6.8E+0

8.18 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast tank inspection to prevent unacceptable long-term risks to the crew performing inspection.

Normal work on deck unrelated to any of the above

8.19 The Group noted that the resulting dose from the exposure from normal work on deck, when compared with a DNEL value, does not lead to an RCR above 1 for any substance (see table 18).

Table 18: Crew, scenario: normal work on deck (1 hour)

Chemical	Scenario "normal work" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	1.7E-7	2.2E-2	7.6E-6
Bromochloroacetic acid	9.4E-10	1.3E+0	7.5E-10
Bromochloroacetonitrile	1.2E-8	1.5E-1	8.0E-8
Chloral hydrate	2.1E-10	6.7E-1	3.2E-10
Chloropicrin	2.6E-6	2.0E-3	1.3E-3
Dalapon	1.4E-9	1.7E-1	8.0E-9
Dibromoacetic acid	2.6E-9	7.2E-2	3.6E-8
Dibromoacetonitrile	3.3E-8	1.6E-1	2.1E-7
Dibromochloroacetic acid	4.3E-10	3.0E-1	1.4E-9
Dibromochloromethane	2.2E-4	2.1E-1	1.0E-3
Dichloroacetic acid	4.3E-10	1.2E-1	3.6E-9
Dichloroacetonitrile	2.3E-7	5.7E-2	4.0E-6
Dichlorobromoacetic acid	1.7E-9	8.6E-1	2.0E-9
Dichlorobromomethane	3.4E-4	4.0E-2	8.4E-3
1,2-Dichloropropane	5.2E-5	8.9E-1	5.9E-5
Monobromoacetonitrile	7.2E-8	8.0E-3	9.0E-6
Tribromoacetic acid	7.4E-9	8.6E-1	8.5E-9
Tribromoacetonitrile*	4.4E-10	3.3E-3	1.3E-7
Tribromomethane	1.8E-3	1.8E-1	9.7E-3
Trichloroacetic acid	6.3E-9	8.6E-1	7.4E-9
Trichloromethane	8.3E-4	5.3E-2	1.6E-2

* Values from the applicant are being used.

8.20 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, normal work on deck does not pose an unacceptable short-term risk to the crew performing the work.

8.21 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was below 1 for all substances (see table 19).

Table 19: Crew, scenario: normal work on deck – DMEL approach

Chemical	Scenario "normal work" (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	1.7E-7	1.1E-4	1.5E-3
Dibromoacetic acid	2.6E-9	1.3E-4	2.0E-5
Dibromochloromethane	2.2E-4	1.5E-3	1.5E-1
Dichloroacetic acid	4.3E-10	1.7E-3	2.5E-7
Dichlorobromomethane	3.4E-4	2.4E-3	1.4E-1
Tribromomethane	1.8E-3	7.7E-3	2.3E-1

8.22 The Group concluded that, as the indicative RCR was below 1 for all substances, normal work on deck does not pose an unacceptable long-term risk to the crew performing the work.

9 RISKS TO THE GENERAL PUBLIC

9.1 The total exposure to the general public whilst swimming in the sea and consuming fish is the sum of the amount of chemical absorbed through consuming fish plus the oral intake, dermal absorption and inhalation absorption whilst swimming (see table 20).

Table 20: General public, scenario: sea bathing and consumption of seafood

Chemical	Scenario 1.1 and 1.2 (µg/kg bw/d)				Aggregated exposure (µg/kg bw/d)	DNEL (µg/kg bw/d)	RCR
	Swimming			Consumption of seafood			
	Oral	Dermal	Inhalation	Oral			
Bromate	5.4E-3	8.3E-2	1.1E-5	3.2E-3	9.2E-2	1.1E+1	8.3E-3
Bromochloroacetic acid	2.0E-4	3.0E-3	6.3E-8	1.9E-3	5.1E-3	6.2E+2	8.2E-6
Bromochloroacetonitrile	1.5E-5	2.3E-4	3.9E-7	1.3E-4	3.8E-4	7.5E+1	5.0E-6
Chloral hydrate	2.3E-4	3.6E-3	1.4E-8	3.5E-3	7.3E-3	3.3E+2	2.2E-5
Chloropicrin	7.1E-6	1.1E-4	6.5E-5	1.7E-4	3.5E-4	1.0E+0	3.5E-4
Dalapon	6.7E-5	1.0E-3	9.1E-8	6.1E-4	1.7E-3	8.4E+1	2.0E-5
Dibromoacetic acid	1.9E-3	3.0E-2	1.8E-7	1.2E-3	3.3E-2	3.6E+1	9.2E-4
Dibromoacetonitrile	2.8E-4	4.3E-3	2.3E-6	8.4E-5	4.7E-3	8.2E+1	5.7E-5
Dibromochloroacetic acid	5.6E-4	8.7E-3	2.9E-8	5.3E-3	1.5E-2	1.5E+2	1.4E-4
Dibromochloromethane	2.4E-4	3.7E-3	5.0E-3	5.0E-3	1.4E-2	1.1E+2	1.3E-4
Dichloroacetic acid	1.6E-4	2.5E-3	2.9E-8	2.0E-4	2.9E-3	6.0E+1	4.8E-5
Dichloroacetonitrile	1.8E-4	2.9E-3	1.5E-5	1.7E-3	4.7E-3	2.9E+1	1.7E-4
Dichlorobromoacetic acid	7.0E-4	1.1E-2	1.2E-7	6.7E-3	1.8E-2	4.3E+2	4.3E-5
Dichlorobromomethane	1.5E-4	2.3E-3	6.5E-3	2.1E-3	1.1E-2	2.0E+1	5.5E-4
1,2-Dichloropropane	1.5E-5	2.3E-4	9.0E-4	3.1E-4	1.5E-3	4.4E+2	3.3E-6
Monobromoacetonitrile	6.6E-5	1.0E-3	4.7E-6	9.9E-4	2.1E-3	4.0E+0	5.2E-4
Tribromoacetic acid	7.2E-3	1.1E-1	4.9E-7	5.4E-2	1.7E-1	4.3E+2	4.0E-4
Tribromoacetonitrile	3.1E-4	4.9E-3	3.0E-8	3.0E-3	8.1E-3	1.7E+0	4.8E-3
Tribromomethane	4.3E-3	6.6E-2	4.7E-2	1.6E-1	2.7E-1	9.0E+1	3.0E-3
Trichloroacetic acid	1.2E-3	1.9E-2	4.2E-7	3.8E-3	2.4E-2	4.3E+2	5.7E-5
Trichloromethane	1.8E-4	2.8E-3	1.4E-2	2.5E-3	1.9E-2	2.6E+1	7.4E-4

9.2 The Group recognized that the resulting doses from the aggregated exposure for the combined scenario for the general public, when compared with DNEL, leads to an RCR below 1 for all substances.

9.3 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk. These values can be used to estimate a risk dose based on the probability of increased cancer incidence over a lifetime (10^{-6}) and may be regarded as a DMEL for the general public.

Table 21: General public, scenario: sea bathing and consumption of seafood – DMEL approach

Chemical	Scenario 1.1 and 1.2 (µg/kg bw/d)				Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	RCR
	Swimming			Consumption of seafood			
	Oral	Dermal	Inhalation	Oral			
Bromate	5.4E-3	8.3E-2	1.1E-5	3.2E-3	9.2E-2	1.1E-1	8.3E-1
Dibromoacetic acid	1.9E-3	3.0E-2	1.8E-7	1.2E-3	3.3E-2	1.3E-1	2.6E-1
Dibromochloromethane	2.4E-4	3.7E-3	5.0E-3	5.0E-3	1.4E-2	1.5E+0	9.3E-3
Dichloroacetic acid	1.6E-4	2.5E-3	2.9E-8	2.0E-4	2.9E-3	1.7E+0	1.7E-3
Dichlorobromomethane	1.5E-4	2.3E-3	6.5E-3	2.1E-3	1.1E-2	2.4E+0	4.6E-3
Tribromomethane	4.3E-3	6.6E-2	4.7E-2	1.6E-1	2.7E-1	7.7E+0	3.5E-2

9.4 The Group noted that the indicative RCR was below 1 for all substances.

10 RISKS TO THE ENVIRONMENT

10.1 Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T)

10.1.1 The Group noted that the applicant had made a listing of P, B and T criteria for the Relevant Chemicals found in the treated ballast water, with results being presented in table 22.

Table 22: PBT properties for selected DBP

	Persistence	Bioaccumulation	Toxicity
Bromate	N.A.	N	N
Bromochloroacetic acid	N.A.	N	N
Bromochloroacetonitrile	N	N	N
Chloral hydrate	N.A.	N	N
Chloropicrin	N.A.	N	Y
Dalapon	N.A.	N	N
Dibromoacetic acid	N	N	N
Dibromoacetonitrile	N.A.	N	N
Dibromochloroacetic acid	N.A.	N	N
Dibromochloromethane	N	N	N
Dichloroacetic acid	N	N	N
Dichloroacetonitrile	Y	N	N
Dichlorobromoacetic acid	N.A.	N	N
Dichlorobromomethane	N	N	N
1,2-Dichloropropane	N.A.	N	N
Monobromoacetonitrile	N.A.	N	N
Tribromoacetic acid	N	N	N
Tribromoacetonitrile	N	N	N
Tribromomethane	N	N	N
Trichloroacetic acid	N	N	N
Trichloromethane	N	N	N

10.1.2 Based on these results, the Group concluded that these chemicals are not PBT substances.

10.2 Calculation of PEC/PNEC ratios

10.2.1 The Group calculated the PEC values and used the maximum PEC concentrations to calculate the PEC/PNEC ratios.

Table 23: PEC/PNEC ratios according to the Group

Chemical name	Harbour			Near sea		
	PEC	PNEC	PEC/ PNEC	PEC	PNEC	PEC/ PNEC
	(µg/L)	(µg/L)	(-)	(µg/L)	(µg/L)	(-)
Bromate	5.1E+0	1.3E+0	4.1E+0	4.1E+1	1.3E+1	3.2E+0
Bromochloroacetic acid	1.9E-1	1.6E+1	1.2E-2	1.5E+0	1.6E+1	9.3E-2
Bromochloroacetonitrile	1.4E-2	6.9E-1	2.1E-2	2.3E-1	6.9E+0	3.3E-2
Chloral hydrate	2.2E-1	9.7E+1	2.3E-3	1.8E+0	9.7E+2	1.8E-3
Chloropicrin	6.8E-3	2.5E-2	2.7E-1	1.4E-1	2.5E-2	5.7E+0
Dalapon	6.5E-2	1.1E+1	5.9E-3	5.1E-1	1.1E+2	4.6E-3
Dibromoacetic acid	1.9E+0	6.9E+0	2.7E-1	1.5E+1	6.9E+1	2.1E-1
Dibromoacetonitrile	2.7E-1	5.5E-2	4.9E+0	2.1E+0	5.5E-1	3.9E+0
Dibromochloroacetic acid	5.4E-1	6.0E+1	8.9E-3	4.2E+0	6.0E+1	7.1E-2
Dibromochloromethane	2.3E-1	6.3E+0	3.6E-2	5.1E+0	2.7E+2	1.9E-2
Dichloroacetic acid	1.6E-1	2.3E+0	6.8E-2	1.2E+0	2.3E+1	5.4E-2
Dichloroacetonitrile	1.8E-1	2.4E+1	7.3E-3	1.5E+0	2.4E+2	6.0E-3
Dichlorobromoacetic acid	6.7E-1	6.0E+1	1.1E-2	5.3E+0	6.0E+1	8.8E-2
Dichlorobromomethane	1.4E-1	7.8E+1	1.8E-3	3.7E+0	2.8E+2	1.3E-2
1,2-Dichloropropane	1.4E-2	4.1E+2	3.5E-5	4.3E-1	4.1E+2	1.0E-3
Monobromoacetonitrile	6.5E-2	2.3E+1	2.8E-3	5.3E-1	2.3E+2	2.3E-3
Sodium thiosulphate	1.0E+2	8.1E+2	1.3E-1	8.0E+2	8.1E+2	9.9E-1
Tribromoacetic acid	7.0E+0	6.0E+1	1.2E-1	5.5E+1	6.0E+1	9.2E-1
Tribromoacetonitrile*	3.0E-1	2.3E-1	1.3E+0	1.2E+0	2.3E+0	5.3E-1
Tribromomethane	4.1E+0	9.6E+1	4.3E-2	7.8E+1	2.9E+2	2.7E-1
Trichloroacetic acid	1.2E+0	6.0E+1	2.0E-2	9.5E+0	6.0E+1	1.6E-1
Trichloromethane	1.8E-1	1.5E+2	1.2E-3	5.3E+0	1.5E+2	3.5E-2

* Values from the applicant are being used.

10.2.2 The Group noted that the PEC/PNEC ratios estimated for the Relevant Chemicals exceeded 1 for four substances (bromate, chloropicrin, dibromoacetonitrile and tribromoacetonitrile). The exceedance, however, is small and due to the worst-case scenario (a dilution factor of 10 instead of 5 would already be sufficient in this near sea scenario) the Group does not expect that under normal operations of the BWMS there will be a risk to the aquatic environment.

11 CONCLUSIONS AND RECOMMENDATIONS

11.1 Risks to ship safety

11.1.1 The Group noted that specific countermeasures have been proposed that can be employed with this BWMS to deal with envisaged emergency and safety problems during the ballast water treatment. The Group recognized that the operating manual presented was not sufficiently detailed and therefore recommended that the operating manual should be updated to include all the information necessary for the crew to operate this BWMS prior to the issuance of a Type Approval Certificate by the Administration.

11.2 Risks to the crew and general public

11.2.1 The Group considered that the use of this BWMS when operated as intended should present no unacceptable risk to the health of the crew and the general public regarding the exposure to chemicals and treated ballast water, based on the results of the performed risk assessment, provided that the considerations and recommendations posed by the Group are addressed.

11.3 Risks to the environment

11.3.1 Having reviewed all of the environmental information submitted with this application for Final Approval, together with the risk assessment performed by the Group, the Group considered that the use of the MARINOMATE™ BWMS will not pose any unacceptable risks for the environment when operated as intended.

11.4 Recommendation

11.4.1 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the MARINOMATE™ Ballast Water Management System. The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

TRO: 10.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of salinity: ≥ 8 PSU.

Applicable range of temperature: > 4°C.

11.4.2 The Group noted that the system is monitored continuously during operation by TRO detectors installed to measure TRO concentrations of treated water and of neutralized deballasting water. The Group further noted that the dosage level of TRO reported for both the land-based tests with marine and brackish water was maintained between 9 and 10 mg/L. However, the Group identified some fluctuation from these parameters. Therefore, the Group recommended that further TRO monitoring improvement be sought by the applicant, including the possible change of sampling point for monitoring.

11.4.3 The Group noted that the BWMS operates at 4°C and 8 PSU. Therefore, the Group concluded that the BWMS has system limitation of salinity at ≥ 8 PSU as measured by a conductivity meter. The Group however recommended the use of a salinity meter for this purpose.

11.4.4 The Group noted that the applicant had installed a gas separator for the removal of hydrogen. The Group recommended that particular care is required when considering the position of ventilation arrangements carrying this gas safely to atmosphere.

11.4.5 The Group recognized that the operating manual presented was not sufficiently detailed and therefore recommended that the operating manual should be updated to include all the information necessary for the crew to operate this BWMS prior to the issuance of a Type Approval Certificate by the Administration.

11.4.6 The Group recommended that the transfer of the neutralizer from the refill tank to the storage tank arrangements should consist of a fixed piping network acceptable to the Administration issuing type approval.

11.4.7 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast water sampling and ballast tank inspection to prevent unacceptable long-term risks to the port State control officers performing sampling and to the crew performing inspection.

11.4.8 The Group recommended that appropriate procedures be developed for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of a full ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of a ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;
- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.

11.4.9 The Group recommended that the residual toxicity should be verified to the satisfaction of the Administration prior to the issuance of the Type Approval Certificate.

ANNEX 5

REVIEW OF PROPOSALS FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES

BlueZone™ Ballast Water Management System

(consisting of disinfection with Active Substance ozone formed in situ,
followed by neutralization with sodium thiosulfate)

Submitted by the Republic of Korea for Final Approval

0 SUMMARY

0.1 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the BlueZone™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

Ozone gas dose: 2.5 mg/L as O₃
TRO: 2.3 mg/L (as Cl₂); and

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂).

0.2 The Group recalled that Basic Approval for this BWMS was granted by MEPC 65 and the report is available as document MEPC 65/2/19, annex 6.

0.3 The Group noted that the BlueZone™ BWMS has been developed by Sunbo Industries Co. Ltd., DSEC Co. Ltd., and the Korean Institute of Machinery and Material (KIMM) and uses the Active Substance ozone, in the form of micro-ozone bubbles (< 50 µm in diameter), to treat the ballast water at uptake. An ozone generator is employed to produce the Active Substance.

0.4 As the BWMS requires the storage of neutralizer sodium thiosulfate on board the ship, the Group reviewed any associated storage safety problems and was satisfied that there should be no unacceptable risks, based on storage provisions developed by the applicant.

0.5 The Group recognized that the applicant has provided information on system controls and safety considerations for installation of the BWMS on board, together with provisions for maintenance and emergency operations of the system. As such, the Group considered that the BWMS should present no unacceptable risks to the safety of the ship during normal use of this BWMS.

0.6 The Group noted that the applicant had performed corrosion testing and the results of this testing indicated that no additional corrosive effect on usual ship construction materials was observed.

0.7 The Group further noted that analytical results for the Active Substance and Other Chemicals in treated ballast water had been provided.

0.8 The Group noted that the applicant had carried out a risk assessment for the crew and the general public based on the Methodology (BWM.2/Circ.13/Rev.1). The Group concluded that there should be no unacceptable risks to human health arising from the use as proposed of this BWMS.

0.9 The Group noted that ozone can be vented on deck at concentrations above the occupational exposure limits (OELs) of 0.2-0.4 mg/m³. The Group further noted that the applicant recommended as a risk mitigation measure to define an exclusion zone of 1 metre around each vent.

0.10 The Group noted that the applicant had calculated the PEC values of the Relevant Chemicals present in ballast water discharged from the system, using MAMPEC-BW model version 3.0. The Group noted that the PEC/PNEC ratios estimated for the Relevant Chemicals exceeded 1 for two substances (chloropicrin and dibromoacetonitrile). However, as explained by the applicant, the concentration of this last substance is elevated due to elevated levels in the source water used in Final Approval as compared to Basic Approval.

0.11 The Group noted that the applicant had provided information on ecotoxicity testing of treated ballast water which did not show any residual effect on any of the species tested.

0.12 The Group recognized that although the PEC/PNEC ratios were not all below 1, the WET tests did not show any effect. In this case, the Group is of the opinion that the results of the WET tests have to be considered more applicable.

0.13 The Group concluded that there should be no unacceptable risks to the environment posed by the use of this BWMS.

0.14 In conclusion, having reviewed all the information provided by the applicant, the Group agreed to recommend to MEPC that Final Approval be granted to the BlueZone™ BWMS.

1 INTRODUCTION

1.1 The data used to evaluate this BWMS were extracted from that supplied by the Republic of Korea in document MEPC 67/2/1, supplemented by the information contained in the confidential application dossier, together with additional information provided by the applicant after a request for further information by the Group during its meeting.

2 DESCRIPTION OF THE SYSTEM

2.1 The Group noted that figure 1 schematically shows the BWMS being reviewed for Final Approval.

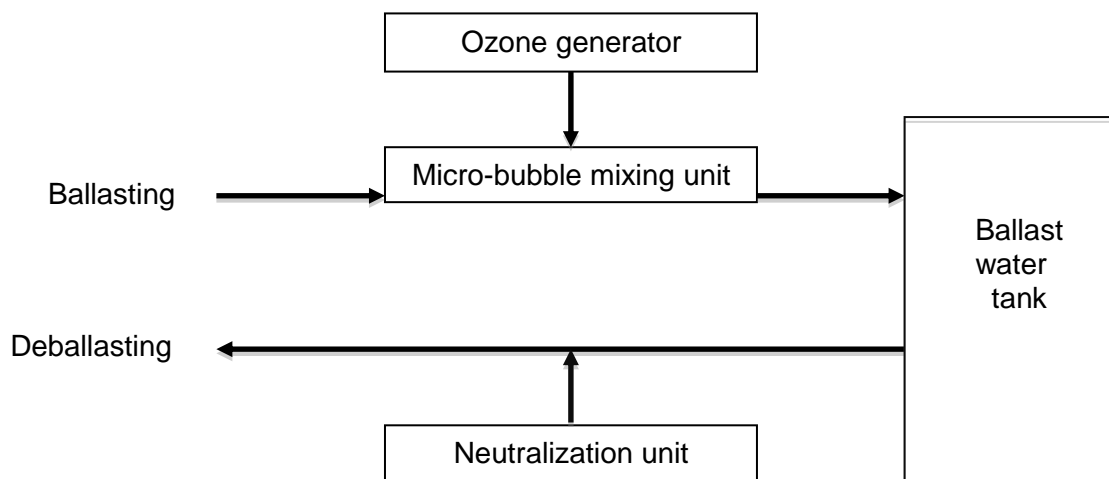


Figure 1: Schematic process diagram of BWMS

2.2 The Group noted that the BlueZone™ BWMS has been developed by Sunbo Industries Co. Ltd., DSEC Co. Ltd., and the Korean Institute of Machinery and Material (KIMM) and uses disinfection with Active Substance ozone, in the form of micro-bubbles, to treat the ballast water at uptake. The Group noted the maximum ozone gas dose of 2.5 mg/L as O₃, which results in a TRO dose of 2.3 mg/L as Cl₂.

2.3 The applicant stated that 5 seconds will be needed to transform TRO from all their micro bubbles in natural seawater. Therefore, the Group was of the opinion that the TRO sensor at its current position could not fully measure the total TRO dose because the ozone gas in the micro-bubbles will not be determined by the DPD method. Therefore, the Group considered that the remaining ozone dose in the micro-bubbles will enter the ballast water tank and will still act as Active Substance in the ballast water tank. The Group recommended that the duration time for ballast water flow between the injection point for ozone gas and the sampling point for TRO monitoring should be greater than 5 seconds, to account for any uncertainties of mixing and reaction rate related to the water conditions.

2.4 The Group noted that the applicant proposed to use a TRO sensor using the DPD colorimetric method. The Group also noted that as a response to the concern expressed in paragraph 2.3, the applicant will employ a different on-line TRO sensor using amperometry in the future. However, at this moment in time, and without any further technological information, the Group has a preference for using the DPD colorimetric method rather than the amperometric method and recommended to use the DPD method, which is originally proposed together with technological information.

2.5 The ozone that is produced is injected into the ballast water through a nozzle producing micro-bubbles with a diameter of less than 50 µm.

2.6 The Group also noted that the neutralization module consists of a neutralizer storage tank, a metering pump (chemical dosing pump) and a nozzle equipped with a back pressure valve. The neutralizing agent, sodium thiosulfate, is injected directly into the ballast water via the pipe and metering pump.

2.7 The Group noted that the TRO sensor cannot measure TRO during the first 2 minutes of deballasting. The Group further noted that the applicant is therefore setting the injection rate of the neutralizer solution at 80 mL/min for these 2 minutes.

3 CHEMICALS ASSOCIATED WITH THE SYSTEM

3.1 The Group noted that in this BWMS the Active Substance is dissolved ozone, for the Group's evaluation purposes expressed as TRO (as Cl₂), and the Relevant Chemicals are the disinfection by-products (DBP).

3.2 The Group noted that the applicant has provided analyses of treated ballast water for the Active Substance and Other Chemicals as part of this application for Final Approval in three salinity regimes: seawater (33 PSU), brackish water (21 PSU) and fresh water (2.7 PSU).

3.3 The Group noted that the results of chemical analysis of the ballast water samples both before and after the neutralization process from this BWMS are provided in tables 1 (seawater and brackish water) and 2 (fresh water).

Table 1: RCs produced by the BWMS in seawater and brackish water

Name of chemical substance	^a MDL	Test water	Elapsed time (day) and concentration								
			Day 0			Day 1			Day 5		
			Control water	^b Treated water		Control water	^b Treated water		Control water	^b Treated water	
				Before ^c N	After N		Before N	After N		Before N	After N
Seawater (33 PSU)											
Bromate	1.2	6.64	6.31	20.41	20.10	3.92	21.57	23.90	6.12	18.43	21.94
Bromochloroacetic acid	0.09	< 0.09	< 0.09	1.52	< 0.09	< 0.09	1.37	1.20	< 0.09	1.59	< 0.09
Chlorate	60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60
Chloropicrin	0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06	< 0.06
Dibromoacetic acid	0.01	3.20	3.19	20.47	11.84	2.91	16.22	13.01	2.40	3.75	4.06
Dibromoacetonitrile	0.08	< 0.08	< 0.08	673.91	2.48	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08
Dibromochloroacetic acid	0.02	1.64	< 0.02	16.31	2.95	1.71	3.17	2.48	< 0.02	3.07	2.48
Dibromochloromethane	0.56	< 0.56	< 0.56	< 0.56	< 0.56	< 0.56	1.95	1.68	< 0.56	2.02	1.87
Dichloroacetic acid	0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Dichlorobromoacetic acid	0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03	< 0.03
Dichlorobromomethane	0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55	< 0.55
Monobromoacetic acid	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Monobromoacetonitrile	0.06	< 0.06	< 0.06	2.16	8.03	< 0.06	22.52	23.53	< 0.06	< 0.06	< 0.06
Monochloroacetic acid	0.04	0.61	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04
Perchlorate	2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09
Thiosulfate, sodium	500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500
Tribromoacetic acid	0.02	1.34	< 0.02	3.13	2.31	1.38	3.33	2.72	1.04	2.56	2.03
Tribromomethane	0.61	< 0.61	< 0.61	30.87	38.15	< 0.61	89.15	79.38	< 0.61	92.80	87.71
2,4,6-Tribromophenol	0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3
Trichloroacetic acid	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Trichloromethane	0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99
1,2,3-Trichloropropane	0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73
Brackish water (21 PSU)											
Bromate	1.2	19.51	15.76	33.55	34.91	19.20	39.05	35.47	12.13	39.82	34.19
Bromochloroacetic acid	0.09	< 0.09	1.53	1.98	1.90	< 0.09	2.35	2.64	1.90	2.12	1.27
Chlorate	60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60
Chloropicrin	0.06	1.54	1.68	< 0.06	1.93	< 0.06	1.39	1.40	< 0.06	1.40	< 0.06

Name of chemical substance	^a MDL	Test water	Elapsed time (day) and concentration								
			Day 0			Day 1			Day 5		
			Control water	^b Treated water		Control water	^b Treated water		Control water	^b Treated water	
				Before ^c N	After N		Before N	After N		Before N	After N
Dibromoacetic acid	0.01	1.90	1.36	17.72	12.29	1.56	9.60	30.61	7.12	14.22	4.10
Dibromoacetonitrile	0.08	< 0.08	< 0.08	57.56	23.80	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08
Dibromochloroacetic acid	0.02	1.84	19.39	26.93	16.94	13.90	12.53	<0.02	16.55	12.59	15.44
Dibromochloromethane	0.56	< 0.56	< 0.56	2.31	2.40	< 0.56	3.73	3.74	< 0.56	3.99	3.44
Dichloroacetic acid	0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Dichlorobromoacetic acid	0.03	< 0.03	< 0.03	0.95	< 0.03	< 0.03	< 0.03	1.03	1.03	0.81	< 0.03
Dichlorobromomethane	0.55	2.99	2.96	3.19	3.16	3.23	3.93	3.89	2.96	4.05	3.40
Monobromoacetic acid	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Monobromoacetonitrile	0.06	< 0.06	< 0.06	0.75	3.97	< 0.06	4.39	4.41	< 0.06	1.51	0.99
Monochloroacetic acid	0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	< 0.04	1.05	< 0.04	< 0.04
Perchlorate	2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09
Thiosulfate, sodium	500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500
Tribromoacetic acid	0.02	< 0.02	< 0.02	4.70	4.86	< 0.02	< 0.02	5.23	< 0.02	2.96	< 0.02
Tribromomethane	0.61	< 0.61	< 0.61	16.55	21.36	< 0.61	62.31	63.02	< 0.61	65.57	48.81
2,4,6-Tribromophenol	0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3
Trichloroacetic acid	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Trichloromethane	0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99	< 0.99
1,2,3-Trichloropropane	0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73

^a: MDL: Method detection limit.

^b: Treated water is divided into two types: before and after neutralization (of the discharge treated water).

^c: N: Neutralization.

Table 2: RCs produced by the BWMS in fresh water

Name of Chemical Substance	^a MDL	Test water	Elapsed Time (day) and Concentration								
			Day 0			Day 1			Day 5		
			Control water	^b Treated water		Control water	^b Treated water		Control water	^b Treated water	
				Before ^c N	After N		Before N	After N		Before N	After N
Freshwater (< 3 PSU)											
Bromate	1.2	< 1.20	< 1.20	13.99	13.94	< 1.20	15.90	11.79	< 1.20	14.18	11.22
Bromochloroacetic acid	0.09	0.84	0.92	0.55	4.33	< 0.09	0.72	2.85	0.82	0.71	0.48
Chlorate	60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60
Chloropicrin	0.06	0.81	1.05	0.87	0.63	0.65	0.83	0.68	0.51	0.73	0.64
Dibromoacetic acid	0.01	0.66	0.68	1.21	0.91	0.65	1.07	1.04	0.68	1.11	< 0.01
Dibromoacetonitrile	0.08	0.39	0.39	5.95	< 0.08	0.29	7.36	1.00	< 0.08	6.70	7.09
Dibromochloroacetic acid	0.02	0.74	0.75	2.05	0.75	0.73	1.06	0.84	0.75	1.05	1.67
Dibromochloromethane	0.56	1.06	< 0.56	1.51	1.03	1.05	2.90	2.46	1.02	3.67	3.18
Dichloroacetic acid	0.02	< 0.02	0.45	0.53	0.50	0.43	0.49	0.50	0.45	0.49	0.38
Dichlorobromoacetic acid	0.03	< 0.03	0.75	0.75	0.75	< 0.03	0.75	< 0.03	0.75	0.75	0.75

Name of chemical substance	^a MDL	Test water	Elapsed time (day) and concentration								
			Day 0			Day 1			Day 5		
			Control water	^b Treated water		Control water	^b Treated water		Control water	^b Treated water	
				Before ^c N	After N		Before N	After N		Before N	After N
Dichlorobromomethane	0.55	4.91	3.85	5.65	3.82	4.24	6.03	5.01	4.36	6.54	5.52
Monobromoacetic acid	0.01	0.30	0.30	0.34	0.31	0.30	0.35	0.33	0.30	0.36	< 0.01
Monobromoacetonitrile	0.06	0.51	0.51	0.46	0.56	0.47	0.48	0.75	0.46	0.47	0.48
Monochloroacetic acid	0.04	0.06	0.07	0.06	0.08	0.06	0.06	0.07	0.06	0.06	< 0.04
Perchlorate	2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09	< 2.09
Thiosulfate, sodium	500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500	< 500
Tribromoacetic acid	0.02	0.74	0.74	0.80	0.75	2.92	0.80	0.80	0.74	0.82	0.76
Tribromomethane	0.61	2.45	1.91	8.67	6.36	2.10	47.37	43.00	2.61	89.72	78.57
2,4,6-Tribromophenol	0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3
Trichloroacetic acid	0.01	< 0.01	< 0.01	< 0.01	1.04	< 0.01	< 0.01	0.85	< 0.01	< 0.01	0.53
Trichloromethane	0.99	13.79	10.93	15.81	10.47	12.92	14.56	11.84	13.50	15.11	12.26
1,2,3-Trichloropropane	0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73	< 0.73

^a: MDL: Method detection limit.

^b: Treated water is divided into two types: before and after neutralization (of the discharge treated water).

^c: N: Neutralization.

3.4 From tables 1 and 2, the Group selected the substances in table 3 for further risk assessment for human health and the environment based on their maximum concentrations. These substances should be considered as the Relevant Chemicals for this BWMS.

Table 3: Selected Relevant Chemicals and maximum concentrations for further risk assessment

Chemical	Concentration (µg/L)
Bromate	4.0E+1
Bromochloroacetic acid	4.3E+0
Chloropicrin	1.9E+0
Dibromoacetic acid	3.1E+1
Dibromoacetonitrile	6.7E+2
Dibromochloroacetic acid	1.7E+1
Dibromochloromethane	4.0E+0
Dichloroacetic acid	5.3E-1
Dichlorobromoacetic acid	1.0E+0
Dichlorobromomethane	6.5E+0
Monobromoacetic acid	3.6E-1
Monobromoacetonitrile	2.4E+1
Tribromoacetic acid	5.2E+0
Tribromomethane	9.3E+1
Trichloromethane	1.6E+1

4 RESPONSE TO THE GESAMP-BWWG REQUESTS

4.1 The Group recalled that it had already provided the following recommendations during its evaluation of the application for Basic Approval of the system (see document MEPC 64/2/6, annex 5) and the applicant had provided the following responses in their Final Approval dossier (see table 4).

Table 4: Applicant's responses to recommendations made by the Group during evaluation for Basic Approval

Section in MEPC 65/2/5, annex 6	Group's Recommendation	Applicant's response	Group's reaction
11.4.2	The Group recommends that further consideration of the process whereby the TRO sensor measures the TRO dose using the DPD method will be needed for the further development of this BWMS.	The BlueZone™ BWMS uses a TRO sensor with the DPD method, which measures the chlorine residual in water. During the land-based testing all TRO was measured with the DPD method, with the results shown in appendix XIII. An emerging technique for TRO measurement is amperometry, which is an electrochemical technique that measures the change in current resulting from chemical reactions. In view of the reliability due to the flow and pressure sensitivity, the BlueZone™ BWMS will employ in the future online TRO sensor using amperometry with improved features such as easier calibration, self-cleaning, reagent-free and fast response (Huntly and Malkov, 2009).	<i>The Group noted the response</i>
11.4.3	The Group recommended that the applicant ensure that the control scheme can maintain the TRO dose and MADC effectively in the full-scale BWMS at all times, and in particular to avoid unacceptable TRO levels at the beginning of discharge.	The control scheme is designed to maintain TRO at 2.3 mg/L at Cl ₂ during ballasting and the remaining TRO concentration of the discharged water lower than MADC as 0.2 mg/L TRO as Cl ₂ during deballasting. This is described in detail in the operation manual in appendix XII, and summarized in section 4.2 in this document. To prevent a high TRO discharge concentration at the beginning of deballasting, the neutralizer solution is injected simultaneously. During the initial 2 minutes of deballasting, TRO is not detected due to the sensor's measurement interval. Therefore, the injection rate of the neutralizer solution is set at 80 mL/min for neutralizing MD (2.3 mg/L TRO as Cl ₂) for the first 2 minutes of deballasting. The initial injection rate (80 mL/min) is obtained by multiplying the calculated value (60 mL/min) by the safety factor (1.3).	<i>The Group was satisfied with the response</i>
11.4.4	The Group recommended additional sampling for chemical	Following the recommendation, additional sampling was made at day 1 for chemical analysis on three types of	<i>The Group was satisfied with the</i>

Section in MEPC 65/2/5, annex 6	Group's Recommendation	Applicant's response	Group's reaction
	analysis between day 0 and day 5 (day 1 or day 2) since the Group is of the opinion that, especially in the case of micro-bubble ozonation, the ozone gas contained in the micro-bubbles in the ballast water tank is expected to produce additional DBPs.	water as fresh, brackish and seawater. The results of chemical analysis on day 1 are shown in tables 3.3 and 3.4 and appendix III, which show similar results to those at day 0 or day 5 except for bromate, bromoform, dibromoacetic acid (DBAA), dibromochloroacetic acid (DBCA) and monobromoacetonitrile, which often were in higher concentrations at day 1 than at day 0 or 5.	<i>response</i>
11.4.5	The Group recommended that all risk mitigation measures to be installed and/or implemented on board are fully detailed in the operating manual to be included in the dossier for Final Approval.	<p>All risk mitigation measures are fully described in the operation and safety manual, appendix XII. The following are included:</p> <ul style="list-style-type: none"> - safety measures for system operation; - definition of pictographs and signal words, action-related hazard warnings; - personnel, local conditions, personal protective equipment, detections of gas; - requirements for the operating personnel, protective equipment, behaviour in emergency situations, installation location; - hazardous substance of ozone, oxygen, neutralizing agents; - health risks and precautions for ozone, oxygen and neutralizing agents; - structured "what if" check list for hazard identification; - possible residual risks such as electrical, thermal hazards; and - safety instructions such as cleaning and maintenance. <p>Safety of personnel and system, regular check list and alarm list of system are described in maintenance section.</p>	<i>The Group was satisfied with the response</i>
11.4.6	The Group noted that a full report of corrosion tests will be included in any application for Final Approval and recommended that corrosion testing, in accordance with the recommendations provided in the revised Methodology, should be performed.	The results of a full-scale corrosion tests are reported in appendix XI. Corrosion testing was carried out for a duration of six months in accordance with the recommendations provided in the section 3.6.9 of the revised Methodology for information gathering and conduct of work of the GESAMP-BWWG' (BWM.2/Circ.13/Rev.1). The results of corrosion tests with an epoxy coated steel specimen show that there was no significant change in performance during the test period of corrosion resistance between the untreated and treated seawater. Also, the results for uncoated metallic specimens 316 L, titanium,	<i>The Group was satisfied with the response</i>

Section in MEPC 65/2/5, annex 6	Group's Recommendation	Applicant's response	Group's reaction
		copper and brass in the control (untreated) and treated seawater were similar to each other. The immersion corrosion test of non-metals showed similar rates of corrosion between the untreated and treated seawater. Non-metals were three types of rubber specimens: NBR, EPDM and VITON(FKM).	
11.4.7	<p>The Group recognized that risk mitigation measures are required for personnel entering ballast water tanks. Considering that the tank may contain a noxious atmosphere in the headspace, the Group recommended that appropriate procedures are developed for tank entry, which may include:</p> <ul style="list-style-type: none"> - Emptying of a full ballast tank and thereby replacing the atmosphere in the tank - Ventilation of a ballast tank prior to personnel entry; - Continuous ventilation during entry; - Respiratory protection; and - Skin and eye protection. 	<p>This question is partly related to 1.1.4 and procedures for entry into ballast water tanks were incorporated into the operation and safety manual, in section 4.15 for mitigating risks. The safety procedures before entering ballast tanks are as follows:</p> <ul style="list-style-type: none"> - ventilation of ballast tanks; - atmosphere monitoring for safety; - preparation and personal protective equipment (PPE) for entry; - arrangement for sufficient rescue and resuscitation equipment available at the enclosed space entrance; and - maintenance of ventilation and illumination while the enclosed space is occupied; 	<i>The Group noted the response</i>

4.2 During the GESAMP-BWWG meeting, the Group posed 16 questions to the applicant. The Group's questions (in **bold text**), the applicant's responses (in plain text) and the reactions of the Group (in *italic text*) are noted below, in numerical order of the individual questions.

Question 1

What does the "Time: 30 min Touch" symbol on page 28 of appendix XII in the confidential application dossier represent?

Response 1

The BlueZone™ BWMS begins to warm up the O₃ destructor as soon as the BWMS is started, which temperature has to reach 400°C to advance to the next stage of O₃ generator PSU (power supply unit) 'On'. If temperature is < 400°C then the system automatically warms up the destructor for an additional 30 minutes. "Touch" means that a manual option is also available, in which the operator can vary the time, either shorten it or lengthen it for warm-up if necessary; this function is available as "Time: 30 min Touch". We plan to replace the heating system in the future with a catalytic system to reduce the warm-up time.

Please note that the flow chart has a typo in that "T > 40°C" should read "T > 400°C".

Group's reaction

The Group was satisfied with the response.

Question 2

In the safety measures outlined in section 4.3 of appendix XII, mention is made of ozone gas detectors. Could the applicant please be more specific in the actions that these alarms would instigate?

Response 2

The following procedures will be added in the safety manual.

- immediately evacuate from the area where the alarm was on;
- make sure that all personnel is out of the area;
- check the ventilation system works properly;
- do not re-enter the area until the alarm is off;
- wear protective gear (gas masks) after the alarm is off; and
- make sure that the system is off and report to authority.

Group's reaction

The Group was satisfied with the response.

Question 3

In section 4.7 of appendix XII, the ozone system is identified as being situated in a well vented machinery or engine-room, but the manual then states that the room for the BWMS shall have an independent ventilation system. Could the applicant describe how the BWMS would be situated in a ship to meet these criteria?

Response 3

We try here to clarify these two sentences:

If the BWMS is installed in a machinery or engine-room, ventilation is always properly maintained by a mechanical vent system. In case the BWMS is installed in a separate room (out of the engine-room) as an independent unit (e.g. container), then an independent vent system will be installed.

Group's reaction

The Group was satisfied with the response.

Question 4

In the SWIFT table given in page 47 of appendix III, the following questions arise:

.1 What functions does the override mode carry out?

Response 4.1

In case of emergency, it is necessary to run the ballast pump without operating the disinfection system. The function is used to operate just the ballast water pump with the ozone disinfection system off. Please see the operation logic in appendix XII, page 33.

Group's reaction

The Group was satisfied with the response.

.2 With a backflow of O₃, what is the warning that will arise and with what consequence?

Response 4.2

In principle, reverse flow of O₃ and seawater is not possible due to the check valve. However, to protect the O₃ generator in case of reverse flow, a liquid and gas separator will turn on as a secondary safeguard, which separates back-flowing seawater and simultaneously triggers an alarm at the seawater detector. The O₃ injection valve at the end of the O₃ generator will be closed, the ventilated ozone destructor valve (VOD valve) will open and back-flowing O₃ gas will be directed to the destructor (appendix XIV, section 1, P&ID). The alarm can be reset and ballasting can resume following checking of the check valve and the liquid and gas separator.

Group's reaction

The Group was satisfied with the response.

.3 If there is an alarm raised from the neutralizer pump, what action is taken?

Response 4.3

The BlueZone™ BWMS is set up to automatically stop deballasting if the neutralizer pump alarm goes on. Undergo an inspection in consultation with trouble and troubleshooting check list provided in appendix xv, section 4. If problem persists, stop deballasting and report to Authorities.

Group's reaction

The Group was satisfied with the response.

Question 5

How is the neutralizer safely delivered, handled and stored?

Response 5

We provide more information, although the general scheme is described in the non-confidential dossier, paragraph 7.1.2. Sodium thiosulfate solution is stored within the BWMS in epoxy coated SS 400 or stainless steel (SUS304) tanks. Extra tanks (PE containers) containing the solution from the supply chain in port cities will be loaded using a crane onto the vessel in the ship's stores. If the solution level in the neutralizer unit of the BWMS is low, crew will use a hand pump to transfer the solution via a hose connecting the container to the BWMS neutralizer tank. Crew should make sure the container is tightly closed and keep the container in a well-ventilated area. When handling, avoid eye contact (irritant) or ingestion. Safety measures for handling are described in the safety manual (appendix XII).

Group's reaction

The Group noted the response.

Question 6

In appendix XVI, the applicant reports the measurement of ozone gas in a defined area surrounding the vent hall of the ballast tank. It is concluded at a distance of 1 metre and should be kept from the air vents in order to avoid ozone concentrations above 0.1 ppmv. Considering these findings for the atmosphere on deck, why does the human health risk assessment not include a consideration of gaseous ozone inside the ballast tank and its implication for the exposure scenarios of sampling, tank cleaning, and tank inspection?

Response 6

Our measurements of ozone gas in the ballast tank show that ozone quickly decays down to near zero within four and half hours. Any activities including cleaning, inspection or sampling are not advised within five hours after ballasting. Even after five hours, before cleaning and inspection, O₃ concentration will be measured with a portable O₃ detector. If the concentration is > 0.1 ppmv, crew should wear protective gear (gas mask), for which procedures are detailed in appendix XII, section 4.15. During sampling, O₃ concentration will be measured with a portable O₃ detector. If the O₃ level is above 0.1 ppmv, workers shall wear gas masks for sampling.

We regarded this as a safety issue, and cannot reply within the 24 hour limit. We will assess the risks posed on human health (DNEL and DMEL) if the Group allows us to do so.

Group's reaction

The Group noted the response.

Question 7

The Group expressed some concerns about quality control of chemical data. As illustrated by the following examples taken from table 3.3 of the non-confidential dossier:

Is the value found for dibromoacetonitrile in seawater day 0 before neutralization realistic or the result of an analytical glitch? Why are identical results provided for dibromoacetic acid and dibromochloroacetic acid in brackish water?

Response 7

The high concentration of dibromoacetonitrile at day 0 in treated seawater was unusual for this time of test and is not the result of an analytical glitch. We had confirmed this through reanalysis of the samples. Please refer to quality control data in appendix III for the data.

IARC (1991) also states about it:

"Halogenated acetonitriles are formed during water disinfection as a result of the reaction of chlorinated oxidizing compounds (e.g. chlorine gas, hypochlorous acid and hypochlorite) with natural organic matter, such as algae, humic substances and proteinaceous material, present in water (IARC, 1991), and particularly nitrogen containing organic compounds in water that contains bromide; it is also a by-product of disinfection by ozonation (Huang et al., 2003, 2004).

Factors that affect the formation of halogenated acetonitriles in drinking-water supplies include water temperature, pH, the dose and type of disinfectant and contact time (IPCS, 2000; Huang et al., 2003; Liang & Singer, 2003; Huang et al., 2004; WHO, 2004)."

We apologize for the mistake in the mis-description of the concentrations of dibromoacetic acid and dibromochloroacetic acid in table 3.3. The correct data on these two chemicals are provided in appendix III, and as shown below.

Chemical substance	Unit	MDL	Test water	Elapsed Time (day) and concentration								
				Day 0			Day 1			Day 5		
				Control water	Treated water		Control water	Treated water		Control water	Treated water	
					Before N	After N		Before N	After N		Before N	After N
Brackish water (21 PSU)												
Dibromoacetic acid (DBAA)	µg/L	0.01	1.90	1.36	17.72	12.29	1.56	9.60	30.61	7.12	14.22	4.10
Dibromochloroacetic acid (DBCA)	µg/L	0.02	1.84	19.39	26.93	16.94	13.90	12.53	< 0.02	16.55	12.59	15.44

Group's reaction

The Group was satisfied with the response.

Question 8

In tables 3.3 and 3.4, an increase of bromoform with time is observed in all tested waters, particularly in fresh water where it ranged from 6-8 (day 0) to 43-47 (day 1) and to 79-90 µg/L (day 5). These results appear rather unusual. Please explain.

Response 8

Bromoform is produced as ozone reacts with dead organisms or other organic materials during disinfection processes. The added concentration of chemicals for DOC and POC are the same for brackish and fresh water. Bromoform concentration generally increases with decreasing pH (Cooper et al., 1986) and the results from both seawater and brackish water are consistent with that.

We don't know the cause for the freshwater data results, but we used tap water (aerated overnight to remove residual TRO), which appears to have contributed to increased pH over the days (possibly due to lack of buffering capacity). The elevated level of bromoform at day 5 might be associated with the complex chemistry of the treated fresh water.

Group	Item	Unit	Test water	Elapsed time (day)								
				Day 0			Day 1			Day 5		
				Control water	Treated water		Control water	Treated water		Control water	Treated water	
					Before N	After N		Before N	After N		Before N	After N
Seawater	Bromoform	µg/L	< 0.61	< 0.61	30.87	38.15	< 0.61	89.15	79.38	< 0.61	92.80	87.71
	pH	-	7.98	7.99	7.98	7.98	7.21	7.70	7.74	7.47	7.12	7.55
Brackish water	Bromoform	µg/L	< 0.61	< 0.61	16.55	21.36	< 0.61	62.31	63.02	< 0.61	65.57	48.81
	pH	-	7.59	7.60	8.18	7.52	7.42	7.91	7.93	6.59	6.43	6.59
Freshwater	Bromoform	µg/L	2.45	1.91	8.67	6.36	2.10	47.37	43.00	2.61	89.72	78.57
	pH	-	7.40	7.42	7.32	7.38	8.85	8.69	8.84	8.52	8.69	8.15

Reference as below:

Cooper, W.J., Amy, G.L., Moore, C.A. and Zilca, R.G. 1986. Bromoform formation in ozonated groundwater containing bromide and humic substances. *Ozone: Science and Engineering: The Journal of the International Ozone Association*, Vol. 8(1); 63-75.
(http://www.tandfonline.com/doi/abs/10.1080/01919518608552304#.U2hJ1fl_s3l).

Group's reaction

The Group was satisfied with the response.

Question 9

Table 6.5 of the non-confidential dossier gives results of the maximum discharge concentration and the calculated MAMPEC concentrations. For sodium bromate, a discharge concentration of 3.98E-2 mg/L leads to a concentration of 1.05 µg/L in the harbour in brackish water. In the calculation for fresh water, a discharge concentration of 1.59E-2 mg/L gives a concentration of 4.17 µg/L in the harbour. As the discharge concentration in the first case is higher one would expect a higher concentration in the harbour water, which is not the case. Please, explain.

Response 9

We apologize for the mistake of the calculated MAMPEC concentrations on sodium bromate in table 6.5. There was an error during data input process of the emission volume of this chemical. We recalculated MAMPEC concentrations for brackish water and freshwater as below and attached the results of the MAMPEC calculation separately. Please also see the attached file for the complete data set 'MAMPEC results on Bromate'.

Chemicals	Seawater (33 PSU)		Brackish water (21 PSU)		Fresh water (2.7 PSU)	
	Max. discharge conc. (mg/L)	PEC (µg/L)	Max. Discharge Conc. (mg/L)	PEC (µg/L)	Max. discharge conc. (mg/L)	PEC (µg/L)
Bromate (Sodium)	2.39E-02	6.27E-01	3.98E-02	1.07E+00	1.59E-02	4.28E-01

Group's reaction

The Group was satisfied with the response.

Question 10

The Group noted that the land-based test at 33 PSU and 21 PSU were carried out in 5 cycles, while that at 2.74 PSU was done in 1 cycle. Please comment.

Response 10

The land-based tests were performed to test the BWMS effectiveness for seawater and brackish water for Guidelines (G8). For Procedure (G9) purposes in accordance with the revised Methodology (paragraph 6.2.2.2), one trial for each of seawater, brackish water, and fresh water was conducted, so the difference in cycle for each

type of water is based on Procedure (G9). Performing the residual toxicity for treated ballast water in fresh water was strongly recommended by the Group in the review of Basic Approval of our BWMS (Question 5 in confidentiality check).

Group's reaction

The Group was satisfied with the response.

Question 11

The Group noted that there was a substantial increase in dibromoacetonitrile in this application compared to Basic Approval of the BlueZone™ BWMS. Does the applicant have an explanation for this increase?

Response 11

We agree that the concentration of dibromoacetonitrile was unexpectedly very high. We think this results from two possible ways: 1) as an unusual case but that can happen, but the results show that the concentration is below MDL especially after neutralization in most cases regardless of seawater, brackish water and fresh water. 2) Another possible reason for this result might be that it reflects the difference of test water used for Basic and Final Approval. Water for Basic Approval was drawn from near Pusan port, whereas the water for Final Approval from Jangmok Bay where the land-based test facility for type approval tests is located.

Group's reaction

The Group was satisfied with the response.

Question 12

The Group noted that dibromoacetonitrile and chloropicrin PEC/PNEC ratios were greater than 1. The Group's calculations for dibromoacetonitrile PEC/PNEC values were 3.3E+2 and 2.5E+2 for harbour and near sea, respectively. Does the applicant have any mitigation measures to control the level of dibromoacetonitrile or is there an explanation as to why this is not a problem?

Response 12

The high PEC/PNEC values for dibromoacetonitrile as the Group noted are due to the high concentration of dibromoacetonitrile. However, the concentration of dibromoacetonitrile after neutralization was down below the level of MDL in most cases and the concentration is similar in range to those observed in treated drinking waters (IARC Monographs Vol. 101, Some Chemicals Present in Industrial and Consumer Products, Food and Drinking-water, see the attached). Maximum human daily exposure to dibromoacetonitrile is at low microgram per kilogram of body weight (IARC Monographs Vol. 101). Therefore, we expect that the ecological risks posed by the BlueZone™ BWMS are limited.

Chemical Substance	Unit	MDL	Test water	Elapsed time (day) and concentration								
				Day 0			Day 1			Day 5		
				Control water	Treated water		Control water	Treated water		Control water	Treated water	
					Before N	After N		Before N	After N		Before N	After N
Dibromoacetonitrile In seawater	µg/L	0.08	< 0.08	< 0.08	673.91	2.48	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08
Dibromoacetonitrile In brackish water	µg/L	0.08	< 0.08	< 0.08	57.56	23.80	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08	< 0.08
Dibromoacetonitrile In fresh water	µg/L	0.08	0.39	0.39	5.95	< 0.08	0.29	7.36	1.00	< 0.08	6.70	7.09

Group's reaction

The Group noted the response.

Question 13

The Group recalled the statements below in the Basic Approval evaluation report (paragraph 2.1.3 in annex 6 of MEPC 65/2/19):

"The Group is of the opinion that the TRO sensor at its current position could not fully measure the total TRO dose because the ozone gas in the micro-bubbles will not be determined by the DPD method. Therefore, the Group considers that the remaining ozone dose in the micro-bubbles will enter the ballast water tank and will still act as Active Substance in the ballast water tank. The Group recommends that further consideration of this process will be needed for the further development of this BWMS."

The Group also noted that ozone gas was detected near the vent holes of the simulated ballast tank used for the land-based test (refer to appendix XVI). From the statement above and the observation, the Group considered that parts of the remaining ozone dose in the ballast water tank will not react as Active Substance, but will only rise to the headspace of the ballast water tank. Please comment. What is your opinion about where the ozone in the headspace of the ballast water tank comes from (up to 0.4 ppm was measured at the vent)?

Also, please clarify the ozone gas utilization in this BWMS with reference to the relationship between the TRO measurement (as mg Cl₂/L) and the total gas dose of ozone (O₃ gas injection g/m³).

Response 13

Ozone in seawater follows the following reaction process, which generally occurs within 5 seconds in seawater (Hoigne et al., 1985; von Gunten, 2003b):



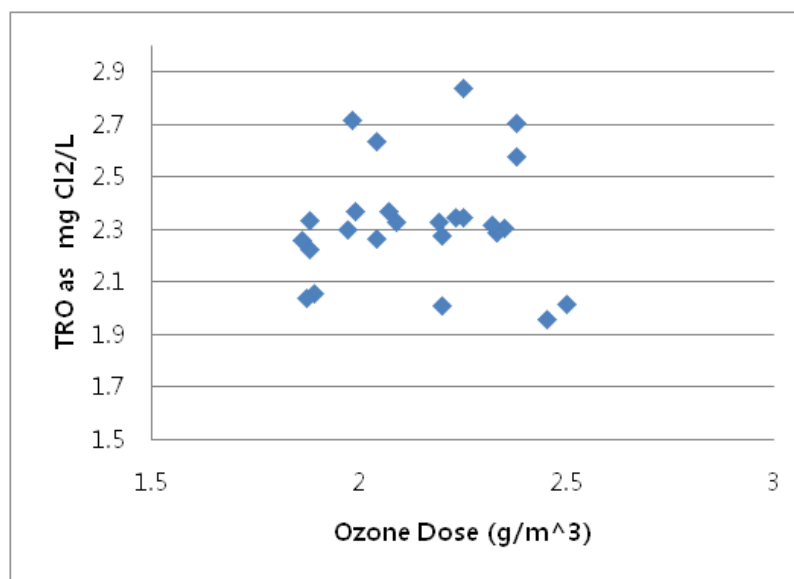
Micro-bubble injection technology is designed precisely to shorten the reaction time by facilitating dissolution of ozone. Therefore, we believe that the location of the TRO sensor would not have affected TRO concentration.

The micro-bubbled ozone may be completely and almost instantly dissolved in micro-bubbled seawater as can be verified in several lines of our data.

- .1 The TRO produced during disinfection exponentially decreases over time. If ozone is trapped inside bubbles, then the TRO concentration in treated seawater will show continuously high and constant level generated during ballasting, then a sharp exponential decline. Our data all demonstrate outright exponential decay of ozone concentration, with no time lag at all.
- .2 We performed an additional experiment of injecting concentrated micro-bubble ozone (approximately 75,000ppmv) to test its solubility. The ozone concentration in the headspace of the ballast water tank was < 1ppmv, a miniscule amount. The utilization rate was calculated at 99.999% $((750000-1)/75000 * 100)$, indicating that the vast majority of ozone was dissolved in seawater.

Ozone measured in the head space would probably be ozone that may have not reacted instantly with seawater with micro bubbling and have escaped to the air. Micro bubbling increases the efficacy of ozone reaction with seawater. The relationship between bubble size and its reaction rate can be verified by peer-reviewed papers in the field of drinking water treatment and waste water treatment. That is, the smaller the size of ozone bubble is, the shorter the reaction time of gaseous ozone in ballast water is and the higher the TRO value in ballast water. Micro bubbling enhances TRO formation compared with that by normal injector for the same amount of ozone injected as reviewed by the Group in Basic Approval of our BWMS (Question 8 in confidentiality check.)

The following graph shows the relationship between the total gas dose of ozone (O_3 gas injection g/m^3 , X-axis) and the TRO measurement (as $mg\ Cl_2/L$, Y-axis). The data are from land-based tests and other previous tests. The average for ozone dose is 2.14 and 2.33 for TRO, showing that the resultant TRO is >100 %, which is consistent with what we pointed out in our response to the Group's question for the submitted data for Basic Approval.



Group's reaction

The Group was satisfied with the response.

Question 14

Can the current TRO sensor detect gas phase ozone (ozone still in micro-bubbles)? If this is not the case, the Group considers that the maximum dose of 2.3 mg TRO/L is underestimated. Please comment.

Response 14

The TRO sensor cannot detect gas phase ozone. Repeating our carefully driven conclusion from above, ozone will be unlikely to be trapped inside micro-bubbles once micro-bubbled ozone reacted with bromine ion in saline water and it almost instantly and completely dissolves in seawater, reacting with bromine ion to produce hypobromide ion. Therefore, the maximum dose is not underestimated.

The maximum dose of 2.3 mg TRO/L is equivalent to 5.175 TRO mg/L as Br₂ (2.3 TRO mg/L as Cl₂ * 2.25 = 5.175 TRO mg/L as Br₂). Our max dose is in similar range used for other BWMS that have already been developed (please see the table below).

Table: TRO measured as Br₂ in various BWMS using ozone disinfection technology

Researcher or developer	TRO (mg/L TRO as Br ₂)	TRO (mg/L TRO as Cl ₂)	Reference
BlueZone	5.175	2.3	
Jake C. Perrins et al.	Max. 4.0 (2.8/3.0)		Ozonation of seawater from different locations: Formation and decay of total residual oxidant—implications for ballast water treatment, Marine Pollution. Bulletin, 2006
Jake C. Perrins et al.	Max. 5.79 (3.50/2.51) Minimal TRO 2.5 upper		Mesocosm experiments for evaluating the biological efficacy of ozone treatment of marine ballast water , Marine Pollution Bulletin 52 (2006) 1756–1767

Researcher or developer	TRO (mg/L TRO as Br ₂)	TRO (mg/L TRO as Cl ₂)	Reference
David A. Wright	4.07/5.73/6.86		Shipboard trials of an ozone-based ballast water treatment system, Marine Pollution Bulletin 60 (2010) 1571–1583
D.J. Oemcke	5 - 11		Ozonation of the marine dinoflagellate alga <i>Amphidinium</i> sp.—implications for ballast water disinfection, Water Research 39 (2005) 5119–5125

Group's reaction

The Group was satisfied with the response.

5 HAZARD PROFILE AND EXPOSURE DATA FOR RELEVANT CHEMICALS

5.1 Predicted No Effect Concentrations (PNEC)

5.1.1 The Group has defined the Relevant Chemicals for which a further risk assessment has to be carried out (see table 3). The Group has used the data available in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water for all substances. The PNECs of the Relevant Chemicals are shown in table 5.

Table 5: PNEC values of Relevant Chemicals

Relevant Chemicals	PNEC harbour (µg/L)	PNEC near sea (µg/L)
Bromate	1.3E+0	1.3E+1
Bromochloroacetic acid	1.6E+1	1.6E+1
Chloropicrin	2.5E-2	2.5E-2
Dibromoacetic acid	6.9E+0	6.9E+1
Dibromoacetonitrile	5.5E-2	5.5E-1
Dibromochloroacetic acid	6.0E+1	6.0E+1
Dibromochloromethane	6.3E+0	2.7E+2
Dichloroacetic acid	2.3E+0	2.3E+1
Dichlorobromoacetic acid	6.0E+1	6.0E+1
Dichlorobromomethane	7.8E+1	2.8E+2
Monobromoacetic acid	1.6E+1	1.6E+1
Monobromoacetonitrile	2.3E+1	2.3E+2
Tribromoacetic acid	6.0E+1	6.0E+1
Tribromomethane	9.6E+1	2.9E+2
Trichloromethane	1.5E+2	1.5E+2

5.2 Derived No Effect Levels (DNEL) and/or Derived Minimum Effect Level (DMEL)

5.2.1 The Group noted the CMR properties associated with the selected Relevant Chemicals (see table 3) and the DNEL/DMEL values to be used in the human risk assessment (see table 6).

Table 6: CMR properties for selected Relevant Chemicals

	Carcinogenic	Mutagenic	Reprotoxicity	CMR
Bromate	1	0	0	1
Bromochloroacetic acid	1	0	1	1
Chloropicrin	0	0	0	0
Dibromoacetic acid	1	1	0	1
Dibromoacetonitrile	0	0	0	0
Dibromochloroacetic acid	0	0	0	0
Dibromochloromethane	1	0	0	1
Dichloroacetic acid	1	0	0	1
Dichlorobromoacetic acid	0	0	0	0
Dichlorobromomethane	1	0	0	1
Monobromoacetic acid	0	0	0	0
Monobromoacetonitrile	0	0	0	0
Tribromoacetic acid	0	0	0	0
Tribromomethane	1	0	0	1
Trichloromethane	0	0	1	1

5.2.2 Based on these results, the Group concluded that some chemicals are CMR substances.

Table 7: DNELs and DMELs to be used in the risk assessment for humans

Chemical	DNEL (mg/kg bw/d) Crew	DNEL (µg/kg bw/d) General public	DMEL (µg/kg bw/d)
Bromate	2.2E-2	1.1E+1	1.1E-4
Bromochloroacetic acid	1.3E+0	6.3E+2	DL
Chloropicrin	2.0E-3	1.0E+0	NA
Dibromoacetic acid	7.2E-2	3.6E+1	1.3E-4
Dibromoacetonitrile	1.6E-1	8.2E+1	NA
Dibromochloroacetic acid	3.0E-1	1.5E+2	NA
Dibromochloromethane	2.1E-1	1.1E+2	1.5E-3
Dichloroacetic acid	1.2E-1	2.9E+1	1.7E-3
Dichlorobromoacetic acid	8.6E-1	4.3E+2	NA
Dichlorobromomethane	4.0E-2	2.0E+1	2.4E-3
Monobromoacetic acid	7.0E-2	3.5E+1	NA
Monobromoacetonitrile	8.0E-3	4.0E+0	NA
Tribromoacetic acid	8.6E-1	4.3E+2	NA
Tribromomethane	1.8E-1	9.0E+1	7.7E-3
Trichloromethane	7.8E-2	2.6E+1	NA

NA = not applicable, substance is not CMR.

DL = data lacking

5.3 Predicted Environmental Concentrations (PEC)

5.3.1 The Group estimated the predicted environmental concentrations (PEC) of chemicals using the Marine Anti-foulant Model to Predict Environmental Concentrations (MAMPEC version 3.0 with the GESAMP-BWWG emission scenario). For the calculation of the PEC, the concentrations mentioned in table 3 in section 3 were used to establish the PEC in the harbour and in the near sea situation. The results are shown in table 8.

Table 8: PEC from MAMPEC modelling results from the GESAMP-BWWG Model Harbour for the harbour and the near sea scenario

Chemical name	PEC (µg/L)	
	Harbour	Near sea
Bromate	1.1E+0	8.5E+0
Bromochloroacetic acid	1.2E-1	9.1E-1
Chloropicrin	1.9E-2	3.9E-1
Dibromoacetic acid	8.3E-1	6.6E+0
Dibromoacetonitrile	1.8E+1	1.4E+2
Dibromochloroacetic acid	4.6E-1	3.6E+0
Dibromochloromethane	3.7E-2	8.2E-1
Dichloroacetic acid	1.4E-2	1.1E-1
Dichlorobromoacetic acid	2.8E-2	2.1E-1
Dichlorobromomethane	5.1E-2	1.3E+0
Monobromoacetic acid	9.7E-3	7.6E-2
Monobromoacetonitrile	6.1E-1	5.1E+0
Tribromoacetic acid	1.4E-1	1.1E+0
Tribromomethane	1.0E+0	1.9E+1
Trichloromethane	1.1E-1	3.2E+0

5.4 Concentration of Relevant Chemicals in the atmosphere

5.4.1 Once the concentrations of chemicals in the ballast tank, and the concentration of chemicals after discharge, that is the predicted environmental concentration (PEC) values as calculated by MAMPEC, have been established, the corresponding concentration of the chemicals evaporating into the air may be calculated (see table 9).

Table 9: Resulting concentrations to be used in the risk assessment for humans

Chemical	Crew		General public	
	Concentration in tank (µg/L)	Concentration in air (mg/m ³)	Concentration MAMPEC (µg/L)	Concentration in air (mg/m ³)
Bromate	4.0E+1	1.6E-5	1.1E+0	4.4E-8
Bromochloroacetic acid	4.3E+0	2.8E-7	1.2E-1	7.8E-10
Chloropicrin	1.9E+0	3.4E-3	1.9E-2	3.4E-6
Dibromoacetic acid	3.1E+1	5.6E-7	8.3E-1	1.5E-9
Dibromoacetonitrile	6.7E+2	1.1E-3	1.8E+1	3.0E-6
Dibromochloroacetic acid	1.7E+1	1.8E-7	4.6E-1	4.8E-10
Dibromochloromethane	4.0E+0	1.6E-2	3.7E-2	1.5E-5
Dichloroacetic acid	5.3E-1	1.8E-8	1.4E-2	4.8E-11
Dichlorobromoacetic acid	1.0E+0	3.2E-8	2.8E-2	9.0E-11
Dichlorobromomethane	6.5E+0	5.6E-2	5.1E-2	4.4E-5
Monobromoacetic acid	3.6E-1	9.6E-9	9.7E-3	2.6E-11
Monobromoacetonitrile	2.4E+1	3.5E-4	6.1E-1	8.8E-7
Tribromoacetic acid	5.2E+0	7.1E-8	1.4E-1	1.9E-10
Tribromomethane	9.3E+1	2.0E-1	1.0E+0	2.2E-4
Trichloromethane	1.6E+1	2.4E-1	1.1E-1	1.6E-4

6 WET TESTS

6.1 The Group noted that the results of WET tests on algae, crustaceans and fish performed by the applicant with 100% treated ballast water after neutralization for seawater (33 PSU), brackish water (21 PSU) and fresh water (2.7 PSU) were presented.

6.2 The Group noted that the results of the WET tests were summarized as in Table 10.

Table 10: Summary of WET tests of treated ballast water after neutralization to test organisms

Test	Test organism	Salinity (PSU)	End points		References/guideline
			NOEC (%)	EC ₅₀ (%) or LC ₅₀	
Algal growth inhibition	<i>Skeletonema costatum</i>	33	100	>100	ASTM E1218/ OECD 201
		21	100	>100	
	<i>Pseudokirchneriella subcapitata</i>	2.7	100	> 100	
Acute rotifer	<i>Brachionus plicatilis</i>	33	100	>100	ASTME 1440
		21	100	>100	
	<i>Brachionus clyciflorus</i>	2.7	100	>100	
Acute fish	<i>Cyprinodon variegatus</i>	33	100	>100	US EPA 821/R02/012
		21	100	>100	
	<i>Oryzias latipes</i>	2.7	100	>100	
Chronic rotifer	<i>Brachionus plicatilis</i>	33	100	>100	Janssen et al., 1994
		21	100	>100	
	<i>Brachionus clyciflorus</i>	2.7	100	>100	
Chronic fish	<i>Cyprinodon variegatus</i>	33	100	>100	US EPA 821/R02/012
		21	100	>100	
	<i>Oryzias latipes</i>	2.7	100	>100	

6.3 The Group noted that no toxicity was shown on any test organisms in the results of WET tests with test water from the BWMS.

6.4 The Group concluded that according to the results of WET tests, there should not be unacceptable effects on the environment.

7 RISKS TO SHIP SAFETY

7.1 The Group noted that some specific countermeasures that can be employed in this BWMS to deal with envisaged emergency and safety problems during the ballast water treatment have been dealt with by the applicant in its response to the recommendations in the Basic Approval evaluation of the Group.

7.2 The Group noted that the applicant proposed a one metre exclusion zone around each ballast tank ventilator to mitigate the risks to personnel in the event of enhanced ozone levels being emitted during the ballasting operation. The Group accepted this precaution as a risk mitigation measure.

7.3 The Group recommended that consideration be given to the risks of the possible ingress of ozone gas in areas such as accommodation, service, control and machinery spaces arising from the location of specific ventilators in relation to these areas.

7.4 The Group noted that a full report of corrosion tests in accordance with the recommendations provided in the Methodology had been included in the application for Final Approval and that no enhanced corrosion had been detected.

7.5 The Group noted that there is an ozone detector in the room containing the ozone generator to detect any leakage of ozone.

8 RISKS TO THE CREW

8.1 The Group noted that the applicant had performed the human risk assessment in accordance with the revised Methodology for information gathering and conduct of work of the GESAMP-BWWG (BWM.2/Circ.13/Rev.1).

8.2 The Group made a risk assessment taking into account the following scenarios from the Methodology in this case:

- .1 delivery, loading, mixing or adding chemicals to the BWMS;
- .2 ballast water sampling;
- .3 periodic cleaning of ballast tanks;
- .4 ballast tank inspections; and
- .5 normal work on deck unrelated to any of the above.

Delivery, loading, mixing or adding chemicals to the BWMS

8.3 The Group noted that the neutralizer solution will be transferred from the storage tank to a feeder tank in the pump-room or engine-room through a refilling pipe.

8.4 The Group recognized that this scenario is not covered by the standard scenario defined in the Methodology such that no quantitative risk assessment is possible. The Group noted however that the applicant proposed that the crew performing this operation should be equipped with PPE.

Ballast water sampling

8.5 The Group noted that the resulting dose from the aggregated exposure from ballast water sampling, when compared with a DNEL value, does not lead to a RCR above 1 for any substance (see table 11).

Table 11: Port State control, scenario: ballast water sampling (2 hours)

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	5.6E-6	6.7E-7	6.3E-6	2.2E-2	2.8E-4
Bromochloroacetic acid	6.0E-7	1.2E-8	6.1E-7	1.2E+0	4.9E-7
Chloropicrin	2.7E-7	1.4E-4	1.4E-4	2.0E-3	7.0E-2
Dibromoacetic acid	4.3E-6	2.4E-8	4.4E-6	7.2E-2	6.1E-5
Dibromoacetonitrile	9.4E-5	4.6E-5	1.4E-4	1.6E-1	8.8E-4
Dibromochloroacetic acid	2.4E-6	7.4E-9	2.4E-6	3.0E-1	7.9E-6
Dibromochloromethane	5.6E-7	6.8E-4	6.8E-4	2.1E-1	3.2E-3
Dichloroacetic acid	7.4E-8	7.6E-10	7.5E-8	1.2E-1	6.2E-7
Dichlorobromoacetic acid	1.4E-7	1.4E-9	1.4E-7	8.6E-1	1.6E-7
Dichlorobromomethane	9.1E-7	2.3E-3	2.3E-3	4.0E-2	5.8E-2
Monobromoacetic acid	5.0E-8	4.0E-10	5.1E-8	7.0E-2	7.3E-7
Monobromoacetonitrile	3.4E-6	1.4E-5	1.8E-5	8.0E-3	2.2E-3
Tribromoacetic acid	7.3E-7	3.0E-9	7.3E-7	8.6E-1	8.5E-7
Tribromomethane	1.3E-5	8.5E-3	8.5E-3	1.8E-1	4.7E-2
Trichloromethane	2.2E-6	9.9E-3	9.9E-3	7.8E-2	1.3E-1

8.6 For the DNEL evaluation the Group concluded that, as the RCR was below 1 for all substances, ballast water sampling does not pose an unacceptable short-term risk to the port State control officers performing sampling.

8.7 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for tribromomethane (see table 12).

Table 12: Port State control, scenario: ballast water sampling – DMEL approach

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	5.6E-6	6.7E-7	6.3E-6	1.1E-4	5.7E-2
Dibromoacetic acid	4.3E-6	2.4E-8	4.4E-6	1.3E-4	3.4E-2
Dibromochloromethane	5.6E-7	6.8E-4	6.8E-4	1.5E-3	4.5E-1
Dichloroacetic acid	7.4E-8	7.6E-10	7.5E-8	1.7E-3	4.4E-5
Dichlorobromomethane	9.1E-7	2.3E-3	2.3E-3	2.4E-3	9.8E-1
Tribromomethane	1.3E-5	8.5E-3	8.5E-3	7.7E-3	1.1E+0

8.8 The Group noted that the largest contribution to the aggregated exposure arises from the inhalation of vapours.

8.9 The Group recommended that adequate respiratory, skin and eye protective devices should be used during ballast water sampling to prevent unacceptable long-term risks to the port State control officers performing sampling.

Periodic cleaning of ballast tanks

8.10 The Group noted that the resulting dose from the aggregated exposure from ballast tank cleaning, when compared with a DNEL value, does not lead to an RCR above 1 (see table 13).

Table 13: Crew, scenario: ballast tank cleaning (8 hours)

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	1.3E-4	2.7E-6	1.3E-4	2.2E-2	6.0E-3
Bromochloroacetic acid	1.4E-5	4.6E-8	1.4E-5	1.25E+0	1.1E-5
Chloropicrin	6.1E-6	5.6E-4	5.7E-4	2.0E-3	2.8E-1
Dibromoacetic acid	1.0E-4	9.4E-8	1.0E-4	7.2E-2	1.4E-3
Dibromoacetonitrile	2.2E-3	1.8E-4	2.4E-3	1.6E-1	1.5E-2
Dibromochloroacetic acid	5.5E-5	3.0E-8	5.5E-5	3.0E-1	1.8E-4
Dibromochloromethane	1.3E-5	2.7E-3	2.7E-3	2.1E-1	1.3E-2
Dichloroacetic acid	1.7E-6	3.0E-9	1.7E-6	1.2E-1	1.4E-5
Dichlorobromoacetic acid	3.2E-6	5.4E-9	3.2E-6	8.6E-1	3.8E-6
Dichlorobromomethane	2.1E-5	9.4E-3	9.4E-3	4.0E-2	2.3E-1
Monobromoacetic acid	1.2E-6	1.6E-9	1.2E-6	7.0E-2	1.7E-5
Monobromoacetonitrile	7.8E-5	5.8E-5	1.4E-4	8.0E-3	1.7E-2
Tribromoacetic acid	1.7E-5	1.2E-8	1.7E-5	8.6E-1	2.0E-5
Tribromomethane	3.0E-4	3.4E-2	3.4E-2	1.8E-1	1.9E-1
Trichloromethane	5.2E-5	4.0E-2	4.0E-2	7.8E-2	5.1E-1

8.11 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, periodic cleaning of ballast tanks does not pose an unacceptable risk to the crew.

8.12 The Group calculated the indicative RCR regarding potential cancer risk as detailed above and noted that the RCR was above 1 for all substances with a DMEL except dibromoacetic acid and dichloroacetic acid (see table 14).

Table 14: Crew, scenario: ballast tank cleaning – DMEL approach

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	1.3E-4	2.7E-6	1.3E-4	1.1E-4	1.2E+0
Dibromoacetic acid	1.0E-4	9.4E-8	1.0E-4	1.3E-4	7.7E-1
Dibromochloromethane	1.3E-5	2.7E-3	2.7E-3	1.5E-3	1.8E+0
Dichloroacetic acid	1.7E-6	3.0E-9	1.7E-6	1.7E-3	1.0E-3
Dichlorobromomethane	2.1E-5	9.4E-3	9.4E-3	2.4E-3	3.9E+0
Tribromomethane	3.0E-4	3.4E-2	3.4E-2	7.7E-3	4.4E+0

8.13 The Group recognized that the scenario "Periodic cleaning of ballast tanks" is the worst-case scenario representing a potential risk to the crew by inhalation and dermal exposure. As this operation is likely to occur on a long-term basis, risk has to be mitigated by implementing operational conditions and using adequate RPE/PPE to reduce exposure as technically achievable.

8.14 The Group noted that the operating manual includes appropriate procedures for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of a full ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of a ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;

- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.

8.15 The Group considered that the proposed mitigation measures mentioned above will also be sufficient to prevent the potential exposure to ozone.

Ballast tank inspection

8.16 The Group noted that the resulting dose from the exposure from the ballast tank inspection, when compared with a DNEL value, does not lead to an RCR above 1 (see table 15).

Table 15: Crew, scenario: ballast tank inspection (3 hours)

Chemical	Scenario "inspection" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	1.0E-6	2.2E-2	4.6E-5
Bromochloroacetic acid	1.7E-8	1.3E+0	1.4E-8
Chloropicrin	2.1E-4	2.0E-3	1.0E-1
Dibromoacetic acid	3.5E-8	7.2E-2	4.9E-7
Dibromoacetonitrile	6.9E-5	1.6E-1	4.3E-4
Dibromochloroacetic acid	1.1E-8	3.0E-1	3.7E-8
Dibromochloromethane	1.0E-3	2.1E-1	4.8E-3
Dichloroacetic acid	1.1E-9	1.2E-1	9.5E-9
Dichlorobromoacetic acid	2.0E-9	8.6E-1	2.4E-9
Dichlorobromomethane	3.5E-3	4.0E-2	8.8E-2
Monobromoacetic acid	6.0E-10	7.0E-2	8.6E-9
Monobromoacetonitrile	2.2E-5	8.0E-3	2.7E-3
Tribromoacetic acid	4.5E-9	8.6E-1	5.2E-9
Tribromomethane	1.3E-2	1.8E-1	7.1E-2
Trichloromethane	1.5E-2	7.8E-2	1.9E-1

8.17 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, ballast tank inspection does not pose an unacceptable short-term risk to the crew performing inspection.

8.18 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for dichlorobromomethane and tribromomethane (see table 16).

Table 16: Crew, scenario: ballast tank inspection – DMEL approach

Chemical	Scenario "inspection" (mg/kg bw/d) Inhalation	DMEL (mg/kg bw/d)	RCR
Bromate	1.0E-6	1.1E-4	9.2E-3
Dibromoacetic acid	3.5E-8	1.3E-4	2.7E-4
Dibromochloromethane	1.0E-3	1.5E-3	6.8E-1
Dichloroacetic acid	1.1E-9	1.7E-3	6.7E-7
Dichlorobromomethane	3.5E-3	2.4E-3	1.5E+0
Tribromomethane	1.3E-2	7.7E-3	1.6E+0

8.19 The Group recommended that adequate respiratory protective devices should be used during ballast tank inspection to prevent unacceptable long-term risks to the crew performing inspection.

8.20 The Group noted that the operating manual includes appropriate procedures for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of a full ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of a ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;
- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.

8.21 The Group considered that the proposed mitigation measures mentioned above will also be sufficient to prevent the potential exposure to ozone.

Normal work on deck unrelated to any of the above

8.22 The Group noted that ozone can be vented on deck at concentrations above the occupational exposure limits (OELs) of 0.2 - 0.4 mg/m³. The Group further noted that the applicant recommended as a risk mitigation measure to define an exclusion zone of 1 metre around each vent.

8.23 The Group considered that occasionally the ozone concentrations can be higher than the OELs therefore the crew has to be aware of the acute health effects associated to these exposure levels in order to promptly identify them while working on deck as part of normal work during ballasting.

8.24 The Group noted that the resulting dose from the exposure from normal work on deck, when compared with a DNEL value, does not lead to an RCR above 1 for any substance (see table 17).

Table 17: Crew, scenario: normal work on deck (1 hour)

Chemical	Scenario "normal work" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	3.4E-8	2.2E-2	1.5E-6
Bromochloroacetic acid	5.8E-10	1.25E+0	4.6E-10
Chloropicrin	7.0E-6	2.0E-3	3.5E-3
Dibromoacetic acid	1.2E-9	7.2E-2	1.6E-8
Dibromoacetonitrile	2.3E-6	1.6E-1	1.4E-5
Dibromochloroacetic acid	3.8E-10	3.0E-1	1.3E-9
Dibromochloromethane	3.4E-5	2.1E-1	1.6E-4
Dichloroacetic acid	3.8E-11	1.2E-1	3.2E-10
Dichlorobromoacetic acid	6.7E-11	8.6E-1	7.8E-11
Dichlorobromomethane	1.2E-4	4.0E-2	2.9E-3
Monobromoacetic acid	2.0E-11	7.0E-2	2.8E-10
Monobromoacetonitrile	7.2E-7	8.0E-3	9.0E-5
Tribromoacetic acid	1.5E-10	8.6E-1	1.7E-10
Tribromomethane	4.2E-4	1.8E-1	2.4E-3
Trichloromethane	4.9E-4	7.8E-2	6.3E-3

8.25 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, normal work on deck does not pose an unacceptable short-term risk to the crew performing the work.

8.26 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was below 1 for all substances (see table 18).

Table 18: Crew, scenario: normal work on deck – DMEL approach

Chemical	Scenario "normal work" (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	3.4E-8	1.1E-4	3.1E-4
Dibromoacetic acid	1.2E-9	1.3E-4	9.0E-6
Dibromochloromethane	3.4E-5	1.5E-3	2.2E-2
Dichloroacetic acid	3.8E-11	1.7E-3	2.2E-8
Dichlorobromomethane	1.2E-4	2.4E-3	4.9E-2
Tribromomethane	4.2E-4	7.7E-3	5.5E-2

8.27 The Group concluded that, as the indicative RCR was below 1 for all substances, normal work on deck does not pose an unacceptable long-term risk to the crew performing the work.

9 RISKS TO THE GENERAL PUBLIC

9.1 The total exposure to the general public whilst swimming in the sea and consuming fish is the sum of the amount of chemical absorbed through consuming fish plus the oral intake, dermal absorption and inhalation absorption whilst swimming (see table 19).

Table 19: General public, scenario: sea bathing and consumption of seafood

Chemical	Scenario 1.1 and 1.2 (µg/kg bw/d)				Aggregated exposure	DNEL (µg/kg bw/d)	RCR
	Swimming			Consumption of seafood			
	Oral	Dermal	Inhalation	Oral			
Bromate	1.2E-3	1.8E-2	2.3E-6	6.9E-4	2.0E-2	1.1E+1	1.8E-3
Bromochloroacetic acid	1.2E-4	1.9E-3	4.0E-8	1.2E-3	3.3E-3	6.2E+2	5.2E-6
Chloropicrin	2.0E-5	3.1E-4	1.8E-4	4.8E-4	9.8E-4	1.0E+0	9.8E-4
Dibromoacetic acid	8.6E-4	1.3E-2	7.8E-8	5.2E-4	1.5E-2	3.6E+1	4.1E-4
Dibromoacetonitrile	1.9E-2	2.9E-1	1.6E-4	5.6E-3	3.2E-1	8.2E+1	3.8E-3
Dibromochloroacetic acid	4.8E-4	7.4E-3	2.5E-8	4.6E-3	1.3E-2	1.5E+2	8.3E-5
Dibromochloromethane	3.8E-5	6.0E-4	7.8E-4	8.0E-4	2.2E-3	1.1E+2	2.0E-5
Dichloroacetic acid	1.5E-5	2.3E-4	2.5E-9	1.8E-5	2.6E-4	6.0E+1	4.3E-6
Dichlorobromoacetic acid	2.9E-5	4.5E-4	4.7E-9	2.8E-4	7.6E-4	4.3E+2	1.8E-6
Dichlorobromomethane	5.3E-5	8.2E-4	2.3E-3	7.7E-4	3.9E-3	2.0E+1	2.0E-4
Monobromoacetic acid	1.0E-5	1.6E-4	1.4E-9	3.0E-6	1.7E-4	3.5E+1	4.9E-6
Monobromoacetonitrile	6.3E-4	9.8E-3	4.6E-5	9.5E-3	2.0E-2	4.0E+0	5.0E-3
Tribromoacetic acid	1.5E-4	2.3E-3	1.0E-8	1.1E-3	3.5E-3	4.3E+2	8.2E-6
Tribromomethane	1.0E-3	1.6E-2	1.1E-2	3.8E-2	6.6E-2	9.0E+1	7.4E-4
Trichloromethane	1.2E-4	1.8E-3	8.5E-3	1.6E-3	1.2E-2	2.6E+1	1.8E-3

9.2 The Group recognized that the resulting doses from the aggregated exposure for the combined scenario for the general public, when compared with DNEL, lead to an RCR below 1 for all substances.

9.3 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk. These values can be used to estimate a risk dose based on the probability of increased cancer incidence over a lifetime (10^{-6}) and may be regarded as a DMEL for the general public.

Table 20: General public, scenario: sea bathing and consumption of seafood – DMEL approach

Chemical	Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	RCR
Bromate	2.0E-2	1.1E-1	1.8E-1
Dibromoacetic acid	1.5E-2	1.3E-1	1.1E-1
Dibromochloromethane	2.2E-3	1.5E+0	1.5E-3
Dichloroacetic acid	2.6E-4	1.7E+0	1.5E-4
Dichlorobromomethane	3.9E-3	2.4E+0	1.6E-3
Tribromomethane	6.6E-2	7.7E+0	8.6E-3

9.4 The Group noted that the indicative RCR was below 1 for all substances.

10 RISKS TO THE ENVIRONMENT

10.1 Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T)

10.1.1 The Group noted that the applicant had made a listing of P, B and T criteria for the Relevant Chemicals found in the treated ballast water, with results being presented in table 21.

Table 21: PBT properties for selected DBP

	Persistence	Bioaccumulation	Toxicity
Bromate	N.A.	N	N
Bromochloroacetic acid	N.A.	N	N
Chloropicrin	N.A.	N	Y
Dibromoacetic acid	N	N	N
Dibromoacetonitrile	N.A.	N	N
Dibromochloroacetic acid	N.A.	N	N
Dibromochloromethane	N	N	N
Dichloroacetic acid	N	N	N
Dichlorobromoacetic acid	N.A.	N	N
Dichlorobromomethane	N	N	N
Monobromoacetic acid	N	N	N
Monobromoacetonitrile	N.A.	N	N
Tribromoacetic acid	N	N	N
Tribromomethane	N	N	N
Trichloromethane	N	N	N

10.1.2 Based on these results, the Group concluded that these chemicals are not PBT-substances.

10.2 Calculation of PEC/PNEC ratios

10.2.1 The Group calculated the PEC values and used the maximum PEC concentrations to calculate the PEC/PNEC ratios.

Table 22: PEC/PNEC ratios according to the Group

Chemical name	Harbour			Near sea		
	PEC	PNEC	PEC/ PNEC	PEC	PNEC	PEC/ PNEC
	(µg/L)	(µg/L)	(-)	(µg/L)	(µg/L)	(-)
Bromate	1.1E+0	1.3E+0	8.5E-1	8.5E+0	1.3E+1	6.5E-1
Bromochloroacetic acid	1.2E-1	1.6E+1	7.5E-3	9.1E-1	1.6E+1	5.7E-2
Chloropicrin	1.9E-2	2.5E-2	7.6E-1	3.9E-1	2.5E-2	1.6E+1
Dibromoacetic acid	8.3E-1	6.9E+0	1.2E-1	6.6E+0	6.9E+1	9.6E-2
Dibromoacetonitrile	1.8E+1	5.5E-2	3.3E+2	1.4E+2	5.5E-1	2.5E+2
Dibromochloroacetic acid	4.6E-1	6.0E+1	7.7E-3	3.6E+0	6.0E+1	6.0E-2
Dibromochloromethane	3.7E-2	6.3E+0	5.9E-3	8.2E-1	2.7E+2	3.0E-3
Dichloroacetic acid	1.4E-2	2.3E+0	6.1E-3	1.1E-1	2.3E+1	4.8E-3
Dichlorobromoacetic acid	2.8E-2	6.0E+1	4.7E-4	2.1E-1	6.0E+1	3.5E-3
Dichlorobromomethane	5.1E-2	7.8E+1	6.5E-4	1.3E+0	2.8E+2	4.6E-3
Monobromoacetic acid	9.7E-3	1.6E+1	6.1E-4	7.6E-2	1.6E+1	4.8E-3
Monobromoacetonitrile	6.1E-1	2.3E+1	2.6E-2	5.1E+0	2.3E+2	2.2E-2
Tribromoacetic acid	1.4E-1	6.0E+1	2.3E-3	1.1E+0	6.0E+1	1.8E-2
Tribromomethane	1.0E+0	9.6E+1	1.0E-2	1.9E+1	2.9E+2	6.6E-2
Trichloromethane	1.1E-1	1.5E+2	7.3E-4	3.2E+0	1.5E+2	2.1E-2

10.2.2 The Group noted that the PEC/PNEC ratios estimated for the Relevant Chemicals exceeded 1 for two substances (chloropicrin and dibromoacetonitrile). According to the Group's calculations for dibromoacetonitrile PEC/PNEC, the exceedance was quite high with values of 3.3E+2 and 2.5E+2 for harbour and near sea, respectively. However, as explained

by the applicant, the concentration of this substance was elevated due to elevated levels in the source water used in Final Approval as compared to Basic Approval.

11 CONCLUSIONS AND RECOMMENDATIONS

11.1 Risks to ship safety

11.1.1 The Group noted that specific risk mitigation measures have been proposed that can be employed with this BWMS to deal with envisaged emergency and safety problems during the ballast water treatment. These have been described and discussed above, and as such, the Group considered that this BWMS should present no unacceptable risks to safety when the BWMS is operated as intended.

11.2 Risks to the crew and general public

11.2.1 The Group considered that the use of this BWMS when operated as intended should present no unacceptable risk to the health of the crew and the general public regarding the exposure to chemicals and treated ballast water, based on the results of the risk assessment performed, provided that the considerations and recommendations posed by the Group are addressed.

11.3 Risks to the environment

11.3.1 Having reviewed all of the environmental information submitted with this application for Final Approval, together with the risk assessment performed by the Group, the Group considered that the use of the BlueZone™ BWMS will not pose any unacceptable risks for the environment when operated as intended, because, although the PEC/PNEC ratios were not all below 1, the WET tests did not show any effect. In this case the Group was of the opinion that the results of the WET tests have to be considered more applicable.

11.3.2 Therefore, the Group does not expect that under normal operations of the BlueZone™ BWMS there will be a risk to the aquatic environment.

11.4 Recommendation

11.4.1 Having reviewed all the data and information submitted by the Republic of Korea with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the BlueZone™ Ballast Water Management System. The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

Ozone gas dose: 2.5 mg/L as O₃
TRO: 2.3 mg/L (as Cl₂); and

- .2 **Maximum allowable discharge concentration of Active Substance** – The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂).

11.4.2 The Group is of the opinion that the TRO sensor at its current position could not fully measure the total TRO dose because the ozone gas in the micro-bubbles will not be determined by the DPD method. Therefore, the Group considers that the remaining ozone dose in the micro-bubbles will enter the ballast water tank and will still act as Active Substance in the ballast water tank. The Group recommended that the duration time for ballast water flow between the injection point for ozone gas and the sampling point for TRO monitoring should be greater than 5 seconds, to account for any uncertainties on mixing and reaction rate related to the water conditions.

11.4.3 The Group recommended that consideration be given to the risks of the possible ingress of ozone gas in areas such as accommodation, service, control and machinery spaces arising from the location of specific ventilators in relation to these areas.

11.4.4 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast water sampling and ballast tank inspection to prevent unacceptable long-term risks to the port State control officers performing sampling and to the crew performing inspection.

ANNEX 6

REVIEW OF PROPOSALS FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES

KURITA™ Ballast Water Management System

(consisting of disinfection with Active Substance sodium hypochlorite
followed by neutralization with sodium sulfite)

Submitted by Japan for Final Approval

0 SUMMARY

0.1 Having reviewed all the data and information submitted by Japan with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the KURITA™ Ballast Water Management System (BWMS). The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – the maximum dose for the Active Substance should be set as follows:

TRO: 20.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance** – the system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of temperature: > 4°C.

0.2 The Group recalled that Basic Approval for the BWMS was granted by MEPC 66 and the report is available as document MEPC 66/2/10, annex 4.

0.3 The Group noted that the KURITA™ BWMS uses the Active Substance sodium hypochlorite to treat the ballast water during uptake. The Group further noted that the applicant intends to provide two different kinds of Active Substance solutions, one with a small amount of phosphate as a corrosion inhibitor added and one Active Substance solution without phosphate.

0.4 The Group also noted that the Active Substance with or without phosphate has to be stored on board. The Group considered that all risk mitigation measures to be put in place related to the storage and handling have been fully detailed in the operating manual that has been developed for this BWMS.

0.5 The Group noted that the applicant proposed that the maximum concentration of chlorate in the Preparation should be below 23 g/L. The Group also noted that the applicant proposed to maintain the temperature of the Preparation during its entire storage time

at 15 or 25°C to maintain the chlorate below the proposed concentration. The Group recommended that a finalized procedure should be developed to the satisfaction of the Administration together with an operating manual to control the temperature of the Preparation.

0.6 As the BWMS requires the storage of neutralizer sodium sulfite in granular form on board the ship, the Group verified and concluded that all risk mitigation measures to be put in place related to the storage and loading of the sodium sulfite neutralizing chemical to the BWMS have been fully detailed in the operating manual that has been developed for this BWMS.

0.7 The Group recognized that the KURITA™ BWMS utilized an Active Substance with potential safety and environmental concerns and the Group reviewed the hazards and risks associated with the Active Substance.

0.8 The Group recognized that the applicant had provided information on system controls and safety considerations for installation of the BWMS on board, together with provisions for maintenance and emergency operations of the system.

0.9 The Group noted that the applicant had performed corrosion testing and the results of this testing indicated that no additional corrosive effect on usual ship construction materials was observed.

0.10 The Group further noted that analytical results for the Active Substance, Relevant Chemicals and Other Chemicals in treated ballast water had been provided.

0.11 The Group noted that the applicant had carried out a risk assessment for the crew and the general public based on the Methodology (BWM.2/Circ.13/Rev.1). The Group concluded that there should be no unacceptable risks to human health arising from the use as proposed of this BWMS.

0.12 The Group noted that the applicant had calculated the PEC values of the Relevant Chemicals present in ballast water discharged from the system, using MAMPEC model version 3.0. The Group noted that the PEC/PNEC ratios estimated for the Relevant Chemicals exceeded 1 for one substance (bromate).

0.13 The Group noted that the applicant had provided information on ecotoxicity testing of treated ballast water which did not show any residual effect on any of the species tested.

0.14 The Group recognized that although the PEC/PNEC ratios were not all below 1, the WET tests did not show any effect. In this case the Group was of the opinion that the results of the WET tests have to be considered more applicable.

0.15 In conclusion, having reviewed all the information provided by the applicant, the Group agreed to recommend to the MEPC that Final Approval be granted to the KURITA™ BWMS.

1 INTRODUCTION

1.1 The data used to evaluate this BWMS were extracted from that supplied by Japan in document MEPC 67/2/2, supplemented by the information contained in the confidential application dossier, together with additional information provided by the applicant after a request for further information by the Group during its meeting.

2 DESCRIPTION OF THE SYSTEM

2.1 The Group noted that figure 1 schematically showed the BWMS being reviewed for Final Approval. During uptake of ballast water, the Preparation solution which includes sodium hypochlorite is added from the storage tank on board to treat the ballast water. The target level of TRO concentration was 20.0 mg TRO/L as Cl_2 .

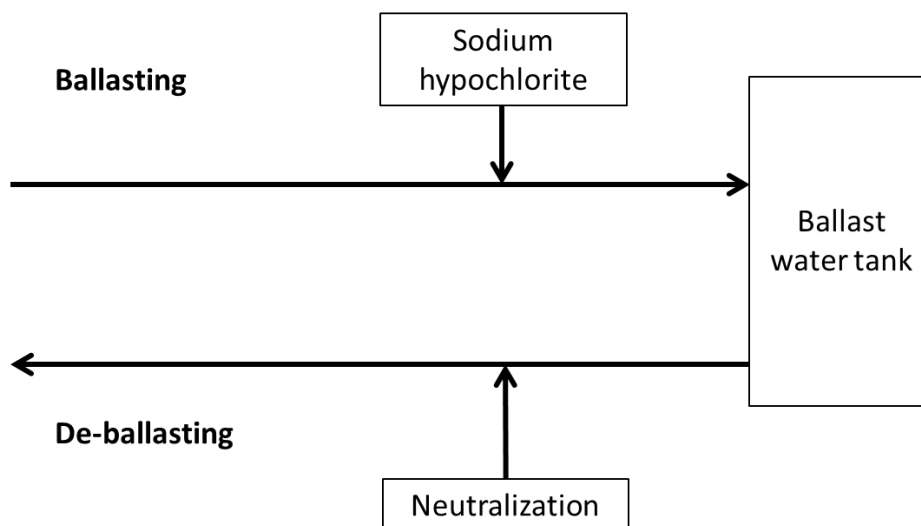


Figure 1: Schematic process diagram of the BWMS

2.2 The Group noted that the applicant had, since the Basic Approval, further developed the dosage control during the land-based testing. The Group noted that during the first five minutes of ballast water treatment, the Preparation is added at a fixed rate according to the ballast water flow. Furthermore, based on the concentration of total residual oxidants (TROs) in the treated water, which is measured with a DPD TRO sensor, the concentration is maintained at not greater than 20.0 mg/L.

2.3 The Group recalled that this BWMS does not contain a filter.

2.4 The added Preparation is mixed with the ballast water by a mixer installed in the main flow. The mixer consists of several multi-hole discs and is installed downstream of the chemical injection point for the preparation and the neutralizer.

2.5 The Group noted that the applicant provides two different kinds of Preparation, one with addition of phosphate at 0.8% as a corrosion inhibitor and one without phosphate.

2.6 The Group recalled that the sodium hypochlorite in the Preparation would be self-decomposing and would be partly transformed to chlorate during tank storage time.

2.7 The Group noted that the applicant proposed that the maximum concentration of chlorate in the Preparation should be below 23 g/L (see paragraph 10.2.3). The Group noted that the applicant proposed to maintain the temperature of the Preparation during its entire storage time at 15 or 25°C to maintain the chlorate below the proposed concentration.

2.8 However, the Group considered that the procedure to maintain the temperature of the Preparation was not fully described by the applicant. Particularly, the Group was of the opinion that manual TRO measurement to check the self-decomposition is impractical on

board and less reliable. Therefore, the Group recommended that the TRO concentration in the Preparation should be regularly monitored by an automatic in-line DPD TRO sensor to check whether the possible chlorate concentration would not reach the criteria mentioned above (< 23 g/L as chlorate). Also, the Group recommended that a finalized procedure should be developed to the satisfaction of the Administration together with an operating manual to control the temperature of the Preparation.

2.9 The Group further noted that the neutralizer solution is added proportionally to the flow rate of the ballast water discharge at 1.6 times the stoichiometric demand. The TRO concentration in the ballast water to be discharged is continuously monitored and recorded using two TRO meters employing the DPD method. The Group also noted that the dosage of the neutralizer is automatically adjusted to the amount determined from the TRO concentration of the first TRO meter and the flow rate of ballast water.

2.10 The first TRO meter is used to monitor TRO in treated ballast water, and the second monitors TRO in discharged ballast water.

2.11 The Group observed that the system could be applicable in seawater, brackish water and fresh water at temperatures above 4°C.

2.12 The Group noted that sodium sulfite as a 10% solution would be stored on board. The Group recommended that the safe storage and handling of this product, along with the methodology for making up the neutralizer solution, be detailed in the operating manual for the BWMS.

2.13 According to the experience of the Group, the volume of the neutralizer solution needed appears to be high for this BWMS. Therefore the Group recommended that it should be confirmed that the tank of the neutralizer Preparation is of a sufficient size to accommodate the discharge operation as intended.

3 CHEMICALS ASSOCIATED WITH THE SYSTEM

3.1 The Group noted that in this BWMS, the Active Substance is sodium hypochlorite in the Preparation, the Relevant Chemicals are the disinfection by-products (DBP), while the Other Chemicals are the neutralization agent sodium sulphite and corrosion inhibitor phosphate which may be added to the Preparation as 0.8%. The Group recognized that in this Final Approval application, TRO is used to describe the amount of sodium hypochlorite present, with TRO calculated as mg Cl₂/L.

3.2 The Group noted that sodium hypochlorite decomposes into sodium chloride and sodium chlorate during the storage of the Preparation on board. The Group, therefore, considered chlorate as a Relevant Chemical.

3.3 The Group noted that the applicant has provided analyses of treated ballast water for Active Substance, Relevant Chemicals and Other Chemicals as part of this application for Final Approval.

3.4 The Group noted that the following substances are stored on board (see table 1).

Table 1: Composition of chemicals used for the KURITA™ BWMS

	Chemical substance	Content (%)
Preparation	Sodium hypochlorite	12
	Phosphate	0-0.8
	Sodium chloride	0-15
	Sodium hydroxide	0-1
	Chlorate	< 23 g/L
Other Chemical	Sodium sulphite	100

3.5 The Group noted that the results of the chemical analysis of the ballast water samples before the neutralization process from this BWMS are provided in tables 2 and 3.

Table 2: Concentration of disinfection by-products produced in seawater and brackish water

Ingredient	DL (µg/L)	Seawater			Brackish water		
		Sample No. 1-0, 1-1, 1-2, 1-5			Sample No. 2-0, 2-1, 2-2, 2-5		
		Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)	Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)
Neutralized discharge water							
Bromate (BrO ₃ -)	10	920	800	97	250	110	89
Bromobenzene	0.1	N.D.	-	-	N.D.	-	-
Bromochloroacetic acid	2	7	4	3	4	3	1
Bromochloroacetonitrile	1	N.D.	-	-	N.D.	-	-
Bromochloromethane	0.1	N.D.	-	-	N.D.	-	-
2,4-Bromophenol	1	N.D.	-	-	N.D.	-	-
2,6-Bromophenol	1	N.D.	-	-	N.D.	-	-
Chloral hydrate	1	N.D.	-	-	N.D.	-	-
Chlorate (ClO ₃ -)	1	790	763	29	760	723	29
Chlorine, free-residual	50	N.D.	-	-	N.D.	-	-
Chlorine, combined- residual	50	N.D.	-	-	N.D.	-	-
Chlorobenzene	0.1	N.D.	-	-	N.D.	-	-
2-Chlorophenol	1	N.D.	-	-	N.D.	-	-
4-Chlorophenol	1	N.D.	-	-	N.D.	-	-
2-Chlorotoluene	0.1	N.D.	-	-	N.D.	-	-
4-Chlorotoluene	0.1	N.D.	-	-	N.D.	-	-
Dibromoacetic acid	2	97	64	24	46	31	13
Dibromoacetonitrile	1	N.D.	-	-	N.D.	-	-
Dibromochloroacetic acid	2	12	9	2	6	4	2
Dibromochloromethane	0.1	30	18	7	1.9	1.5	0.8
1,2-Dibromo-3-chloropropane	0.1	N.D.	-	-	N.D.	-	-
1,2-Dibromoethane	0.1	N.D.	-	-	N.D.	-	-
Dibromomethane	0.1	N.D.	-	-	N.D.	-	-
Dichloroacetic acid	2	N.D.	-	-	N.D.	-	-
Dichloroacetonitrile	1	N.D.	-	-	N.D.	-	-
Dichloroamine	50	N.D.	-	-	N.D.	-	-
o-Dichlorobenzene	0.1	N.D.	-	-	N.D.	-	-
m-Dichlorobenzene	0.1	N.D.	-	-	N.D.	-	-
p-Dichlorobenzene	0.1	N.D.	-	-	N.D.	-	-
Dichlorobromoacetic acid	2	N.D.	-	-	N.D.	-	-
Dichlorobromomethane	0.1	0.7	0.45	0.15	11	7	3

Ingredient	DL (µg/L)	Seawater			Brackish water		
		Sample No. 1-0, 1-1, 1-2, 1-5			Sample No. 2-0, 2-1, 2-2, 2-5		
		Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)	Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)
1,1-Dichloroethane	0.1	N.D.	-	-	N.D.	-	-
1,2-Dichloroethene	0.1	N.D.	-	-	N.D.	-	-
1,1-Dichloroethene	0.1	N.D.	-	-	N.D.	-	-
cis-1,2-Dichloroethene	0.1	N.D.	-	-	N.D.	-	-
trans-1,2-Dichloroethene	0.1	N.D.	-	-	N.D.	-	-
Dichloromethane	0.1	N.D.	-	-	N.D.	-	-
2,4-Dichlorophenol	1	N.D.	-	-	N.D.	-	-
2,6-Dichlorophenol	1	N.D.	-	-	N.D.	-	-
cis-1,-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
trans-1,-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
1,1-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
1,2-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
1,3-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
2,2-Dichloropropane	0.1	N.D.	-	-	N.D.	-	-
2,2-Dichloropropionic acid	1	N.D.	-	-	N.D.	-	-
Formaldehyde	1	6	5	1	1	0.3	0.4
Monobromoacetic acid	2	10	6	4	4	2	2
Monochloroacetic acid	2	2	1	1	2	2	0
Monochloroamine	50	N.D.	-	-	N.D.	-	-
1,1,1,2-Tetrachloroethane	0.1	N.D.	-	-	N.D.	-	-
1,1,2,2-Tetrachloroethane	0.1	N.D.	-	-	N.D.	-	-
Tetrachloroethene	0.1	N.D.	-	-	N.D.	-	-
Tetrachloromethane	0.1	N.D.	-	-	N.D.	-	-
Tribromoacetic acid	2	150	117	30	53	24	18
Tribromomethane	0.1	890	503	236	130	91	30
2,4,6-Tribromophenol	1	N.D.	-	-	N.D.	-	-
Trichloroacetic acid	2	N.D.	-	-	N.D.	-	-
Trichloroacetonitrile	1	N.D.	-	-	N.D.	-	-
1,2,3-Trichlorobenzene	0.1	N.D.	-	-	N.D.	-	-
1,2,4-Trichlorobenzene	0.1	N.D.	-	-	N.D.	-	-
1,1,1-Trichloroethane	0.1	N.D.	-	-	N.D.	-	-
1,1,2-Trichloroethane	0.1	N.D.	-	-	N.D.	-	-
Trichloroethene	0.1	N.D.	-	-	N.D.	-	-
Trichloromethane	0.1	N.D.	-	-	1.9	0.9	1
2,4,6-Trichlorophenol	1	N.D.	-	-	N.D.	-	-
1,2,3-Trichloropropane	0.1	N.D.	-	-	N.D.	-	-
Vinyl chloride	0.1	N.D.	-	-	N.D.	-	-

DL: Detection limit.

N.D.: Not detected.

Table 3: Concentration of disinfection by-products produced in fresh water

Ingredient	DL (µg/L)	Fresh water		
		Sample No. 3-0, 3-1, 3-2, 3-5		
		Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)
Neutralized discharge water				
Bromate (BrO ₃ ⁻)	10	N.D.	-	-
Bromobenzene	0.1	N.D.	-	-
Bromochloroacetic acid ^{b)}	2	6	5	1
Bromochloroacetonitrile	1	N.D.	-	-
Bromochloromethane	0.1	N.D.	-	-
2,4-Bromophenol	1	N.D.	-	-
2,6-Bromophenol	1	N.D.	-	-
Chloral hydrate	1	N.D.	-	-
Chlorate (ClO ₃ ⁻)	1	740	713	16
Chlorine, free-residual	50	N.D.	-	-
Chlorine, combined- residual	50	N.D.	-	-
Chlorobenzene	0.1	N.D.	-	-
2-Chlorophenol	1	N.D.	-	-
4-Chlorophenol	1	N.D.	-	-
2-Chlorotoluene	0.1	N.D.	-	-
4-Chlorotoluene	0.1	N.D.	-	-
Dibromoacetic acid	2	N.D.	-	-
Dibromoacetonitrile	1	N.D.	-	-
Dibromochloroacetic acid	2	2	1	1
Dibromochloromethane	0.1	7.4	4.8	2.0
1,2-Dibromo-3-chloropropane	0.1	N.D.	-	-
1,2-Dibromoethane	0.1	N.D.	-	-
Dibromomethane	0.1	N.D.	-	-
Dichloroacetic acid	2	18	13	4
Dichloroacetonitrile	1	N.D.	-	-
Dichloroamine	50	N.D.	-	-
o-Dichlorobenzene	0.1	N.D.	-	-
m-Dichlorobenzene	0.1	N.D.	-	-
p-Dichlorobenzene	0.1	N.D.	-	-
Dichlorobromoacetic acid	2	10	5	3
Dichlorobromomethane	0.1	5.9	3.4	1.6
1,1-Dichloroethane	0.1	N.D.	-	-
1,2-Dichloroethene	0.1	N.D.	-	-
1,1-Dichloroethene	0.1	N.D.	-	-
cis-1,2-Dichloroethene	0.1	N.D.	-	-
trans-1,2-Dichloroetene	0.1	N.D.	-	-
Dichloromethane	0.1	N.D.	-	-
2,4-Dichlorophenol	1	N.D.	-	-
2,6-Dichlorophenol	1	N.D.	-	-
cis-1,-Dichloropropane	0.1	N.D.	-	-
trans-1,-Dichloropropane	0.1	N.D.	-	-
1,1-Dichloropropane	0.1	N.D.	-	-
1,2-Dichloropropane	0.1	N.D.	-	-
1,3-Dichloropropane	0.1	N.D.	-	-
2,2-Dichloropropane	0.1	N.D.	-	-
2,2-Dichloropropionic acid	1	N.D.	-	-
Formaldehyde	1	N.D.	-	-
Monobromoacetic acid	2	N.D.	-	-

Ingredient	DL (µg/L)	Fresh water		
		Sample No. 3-0, 3-1, 3-2, 3-5		
		Maximum value (µg/L)	Mean value (µg/L)	Standard deviation (µg/L)
Monochloroacetic acid	2	2	2	0
Monochloroamine	50	N.D.	-	-
1,1,1,2-Tetrachloroethane	0.1	N.D.	-	-
1,1,2,2-Tetrachloroethane	0.1	N.D.	-	-
Tetrachloroethene	0.1	N.D.	-	-
Tetrachloromethane	0.1	N.D.	-	-
Tribromoacetic acid	2	N.D.	-	-
Tribromomethane	0.1	0.6	0.4	0.2
2,4,6-Tribromophenol	1	N.D.	-	-
Trichloroacetic acid	2	20	13	5
Trichloroacetoneitrile	1	N.D.	-	-
1,2,3-Trichlorobenzene	0.1	N.D.	-	-
1,2,4-Trichlorobenzene	0.1	N.D.	-	-
1,1,1-Trichloroethane	0.1	N.D.	-	-
1,1,2-Trichloroethane	0.1	N.D.	-	-
Trichloroethene	0.1	N.D.	-	-
Trichloromethane	0.1	18	13	3
2,4,6-Trichlorophenol	1	N.D.	-	-
1,2,3-Trichloropropane	0.1	N.D.	-	-
Vinyl chloride	0.1	N.D.	-	-

DL: Detection limit.

N.D.: Not detected.

3.6 From tables 2 and 3, the Group selected the substances in table 4 based on their maximum concentrations for further risk assessment for human health and the environment. These substances should be considered the Relevant Chemicals for this BWMS.

Table 4: Selected Relevant Chemicals and maximum concentrations for further risk assessment

Chemical	Concentration (µg/L)
Bromate	9.2E+2
Bromochloroacetic acid	7.0E+0
Chlorate	7.9E+2
Dibromoacetic acid	9.7E+1
Dibromochloroacetic acid	1.2E+1
Dibromochloromethane	3.0E+1
Dichloroacetic acid	1.8E+1
Dichlorobromoacetic acid	1.0E+1
Dichlorobromomethane	1.1E+1
Formaldehyde	6.0E+0
Monobromoacetic acid	1.0E+1
Monochloroacetic acid	2.0E+0
Tribromoacetic acid	1.5E+2
Tribromomethane	8.9E+2
Trichloroacetic acid	2.0E+1
Trichloromethane	1.8E+1

4 RESPONSE TO THE GESAMP-BWWG REQUESTS

4.1 The Group recalled that it had already provided the following recommendations during its evaluation of the application for Basic Approval of the system (see document MEPC 66/2/10, annex 4), and the applicant had provided the following responses in their Final Approval dossier (see table 5).

Table 5: Applicant's responses to recommendations made by the Group during evaluation for Basic Approval

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
11.4.2	The Group recommended that the Maximum Allowable Dosage should be kept at 20.0 mg/L for the further development of this BWMS and further recommended that all tests performed for any future application for Final Approval should be conducted with the proposed dose of 20.0 mg/L.	<p>In the application for Basic Approval, the maximum allowable dosage of the biocide added to the KURITA™ BWMS was described finally as 20 mg/L as Cl₂. However, in individual tests, assessments were made with a chlorine concentration inside the ballast water piping of approximately 30 mg/L as Cl₂. In the application for Final Approval, the chlorine concentration inside the ballast water piping of the land-based test equipment was controlled to 20 mg/L or lower and all the tests, including the analysis of by-products and toxicity tests on aquatic organisms, were performed under that condition with collected test waters.</p> <p>The following is a description of MADC control with the land-based test equipment. Figure 1.1 illustrates the outline of the treatment flow with the KURITA™ BWMS. During the first five minutes of ballast water treatment, the biocide is added at a fixed rate according to the ballast water flow measured by a flow meter (F1) so that the biocide concentration is kept to 20 mg/L as Cl₂. Then, based on the concentration of total residual oxidants (TROs) in the treated water measured with a TRO analyser (TRO1), the concentration is maintained to not greater than 20.0 mg/L via proportional integral derivative (PID) control. The land-based test equipment controlled in that way could maintain the TRO concentration to not greater than 20 mg/L as Cl₂ during ballasting as shown in figure 1.2.</p> <p><i>The figures have been removed from the response</i></p>	<i>The Group was satisfied with the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
11.4.3	The Group noted that the applicant did not provide any technical information for the mixer, which is installed in the ballast water piping, and recommended that this should be included in any future application for Final Approval.	The mixer used in the KURITA™ BWMS consists of several multi-hole discs, with an internal diameter equal to that of the ballast water piping, which are installed at the downstream of the chemical feed point for the biocide and the neutralizer. It does not use power for mixing. Each disc causes a narrowing of the flow after the multi-hole outlet, which increases the centreline velocity. The velocity at the multi-hole outlet takes a distribution form that reaches its maximum near the outer edge and the whirling flow rate increases because a large shear stress is generated at the outer edge of the jet stream. Therefore, in spite of the small pressure loss, the mixer is excellent in mixing and diffusion characteristics. Details are explained in section 4.3.	<i>The Group was satisfied with the response</i>
11.4.4	The Group recommended that further assessment be performed to establish an optimized overdose ratio particularly in cold water.	<p>In the application for Basic Approval, assessments were made for the neutralization of the TROs in treated ballast water at a low temperature (4°C) to below the MADC with sodium sulfite. The results revealed that 1.4 times the theoretical neutralization equivalent failed and 2.4 times succeeded in their neutralization. However, only those two data sets were available for the low temperature condition; therefore, the application stated that the optimal quantity of the neutralizer had yet to be considered.</p> <p>In this application for Final Approval, laboratory-based tests were made on the required quantity of the neutralizer between 4°C and 25°C with seawater, brackish water and fresh water. The results have confirmed that the optimal quantity of the neutralizer is 1.6 times the theoretical neutralization equivalent. The details of the results are described in section 2.3.2.</p>	<i>The Group was satisfied with the response</i>
11.4.5	The Group recommended that for further development of this BWMS, the applicant ensured that the control scheme could maintain the TRO dose and the MADC effectively in the full-scale BWMS at all times, and in particular	<p>The KURITA™ BWMS takes the following measures to prevent the TRO quantity from increasing to an unacceptable level at the initial stage of deballasting. The details are described based on figure 1.1 illustrating the outline of the treatment flow of the system.</p> <p>To prevent the high concentration of TROs inside the piping between the neutralizer feed point and the outlet of</p>	<i>The Group was satisfied with the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
	to avoid unacceptable TRO levels at the beginning of discharge. The Group considered that the treated ballast water could have significant risks to the marine environment if it was discharged without neutralization.	<p>ballast water, the KURITA™ BWMS introduces neutralizer into the piping for one minute at a fixed rate before starting to operate the ballast pump. The quantity of neutralizer is 1.6 times that which would be required to reduce TROs of 20 mg/L as Cl₂ to below 0.2 mg/L as Cl₂. For five minutes after the ballast pump starts to operate, neutralizer continues to be added in the same way as described above. The subsequent dosage of neutralizer is calculated from the flow rate measured by the flow meter and the TRO concentration inside the treated ballast water piping measured by the TRO1 analyser. To guarantee neutralization of the TROs in the treated ballast water to be discharged, the dosage of neutralizer is set to 1.6 times the quantity required for their neutralization.</p> <p>The control procedure described above is started with deballasting. Then, pressing the relevant button on the touch panel initiates the continuous automatic neutralization process. The results of the land-based tests with that control method have confirmed that the TRO concentration during deballasting as indicated on the TRO2 analyser remains below the MADC, as shown in figure 1.3.</p> <p><i>The figure has been removed from the response</i></p>	
11.4.6	The Group recommended that the safe storage and handling of the neutralizer, along with the methodology for making up the neutralizer solution, is detailed in the operating manual for the BWMS. The Group also recommended that the ballast water treatment neutralization process is made fully automatic and that the control system for this procedure be further considered for the	<p>.1 Loading and storage method</p> <p>Sodium sulfite (neutralizer) is loaded onto the ship with a crane in a 25 kg paper bag or a 100 L/500 L/1,000 L flexible container bag. It should be stored in a cool dark place with sufficient ventilation, avoiding exposure to direct sunlight. Load shifting due to ship swaying or rolling should be prevented by installing a dedicated storage cabinet with a stand for the neutralizer in the storage space. In addition, it is necessary to take measures so that the neutralizer remains dry if the floor gets flooded.</p> <p>.2 Handling method</p> <p>To prevent inhalation as well as to</p>	<i>The Group noted the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
	further development of this BWMS.	<p>protect their eyes and skin, workers should wear Personal Protective Equipment (PPE), such as long-sleeve work clothes, protective goggles, chemical-resistant rubber gloves, rubber boots, rubber clothes and a protective mask, before starting work.</p> <p>Contact of neutralizer with acids, such as inorganic strong acids and organic acids, must be avoided because a considerable amount of SO_x is generated when they are mixed.</p> <p>Spent containers must not be reused for other purposes such as beverage containers.</p> <p>.3 Neutralizer solution preparation method</p> <p>A neutralizer dissolving tank is filled with a predetermined amount of fresh water, and then the neutralizer is added while mixing so that the neutralizer concentration becomes 10%. Preparation should be carried out when the liquid level indicator of the neutralizer dissolving tank is at the "L" position. By this method the amount of neutralizer and water can be constant for every preparation. An exact amount of neutralizer for one Preparation should be used. Fresh water stored in a fresh water tank of the ship is used.</p> <p>As a measure to avoid contamination of the fresh water tank by the neutralizer, fresh water is added from an upper part of the neutralizer dissolving tank to prevent the outlet of fresh water piping from contacting the neutralizer solution. A check valve is also installed in the fresh water piping.</p> <p>In the case of neutralizer provided in a flexible container bag, the bag is carried and suspended over the neutralizer dissolving tank using a hoist crane and chain block, and the rope of the outlet at the bottom of the bag is untied to load the chemical from above. A hopper is installed over the neutralizer dissolving tank to facilitate this work.</p>	

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
		<p>In the case of neutralizer provided in a 25 kg paper bag, the bag is carried and suspended over the neutralizer dissolving tank and opened to load the chemical. After the whole amount of neutralizer is added, mixing continues in order to dissolve the neutralizer. The prepared neutralizer solution is transferred to the separate neutralizer storage tank with a neutralizer transfer pump, and added into the ballast water piping from the neutralizer storage tank with a neutralizer feed pump. The above neutralizer handling method and its solution preparation method are described in the operating manual of the KURITA™ BWMS.</p> <p>As described in section 1.1.4, continuous, automatic ballast water neutralization is started by pressing the relevant button on the KURITA™ BWMS touch panel.</p>	
11.4.7	The Group recommended the applicant provide ecotoxicity testing with treated fresh water in any future application for Final Approval. The Group recommended that the WET tests on treated and neutralized discharge water to be performed for Final Approval should be carried out under QA/QC in accordance with the revised Methodology.	In this application for Final Approval, assessments were made in accordance with the Methodology for information gathering and conduct of work of the GESAMP-BWWG (the Methodology) (BWM.2/Circ.13/Rev.1) on neutralized, treated fresh water with algae because toxic effects will appear most obviously in that scenario. According to the results, the EC ₅₀ was > 100% and the NOEC was ≥ 100% and, thus, no growth inhibition was observed. The details including other WET test results are described in section 8.2.2.3.	<i>The Group noted the response</i>
11.4.8	The Group recommended that all risk mitigation measures to be installed and/or implemented on board are fully detailed in the operating manual to be included in the application for Final Approval.	<p>The operating manual of the KURITA™ BWMS describes the outline and details of the system configuration and notes its critical parts individually in chemical-related, equipment-related, operation-related and maintenance-related sections with work contents, implementation frequencies and safety measures.</p> <p>In addition, to reduce risks caused by human errors, prior safety training is planned for operators and maintenance personnel to deepen their knowledge about the system.</p>	<i>The Group noted the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
11.4.9	The Group recommended that the testing procedures involving simulated ballast tank conditions be carried out on both bare steel and surfaces with PSPC compliant coatings and also with test mediums of treated ballast water with and without phosphate.	<p>Corrosion tests were performed in accordance with the Methodology (BWM.2/Circ.13/Rev.1) on PSPC coated steel plates and other materials, including uncoated metals, which may be used in ships with both phosphate-doped and phosphate-free biocides. In all the test sections with seawater, brackish water and fresh water using phosphate-doped and phosphate-free biocides, the test results fulfilled the acceptance criteria and there was hardly any significant difference in corrosive effect on hull materials compared to untreated water. Thus, the corrosion impact of the biocide on hull materials can be considered to be tolerable. Moreover, the anti-corrosive effect of phosphate contained in the biocide was confirmed in crevice corrosion tests with inorganic coated metal materials. The details of the test results are described in section 3.2.</p> <p>Further consideration will be given to conditions to optimize the anti-corrosive effect of phosphate on hull materials.</p>	<i>The Group noted the response</i>
11.4.10	The Group recommended that appropriate procedures be developed for tank entry to prevent unacceptable risks to the crew.	<p>To prevent ship crew from coming into contact with the Active Substances and Relevant Chemicals, the following hazard prevention rules, to be strictly observed when entering the ballast tank, were added to the operating manual of the KURITA™ BWMS:</p> <ol style="list-style-type: none"> .1 empty the ballast tank and leave the maintenance hatch open. Then, over a period of at least one hour, replace the air inside the ballast tank with fresh air using fans; .2 just before entering the ballast tank, check chlorine, oxygen, carbon monoxide, methane and hydrogen sulfide gas concentrations with gas detectors; .3 if any problems are discovered in the above gas concentrations, continue ventilation until they are reduced to a level that is harmless to human health; .4 continue ventilation while anybody is in the ballast tank; 	<i>The Group noted the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
		<p>.5 wear appropriate PPE such as safety helmets, safety belt, long-sleeve work clothes, protective goggles, chemical-resistant rubber gloves, rubber boots, rubber clothes and a protective mask to prevent the inhalation of halogen gases and organic gases;</p> <p>.6 have resuscitators and respirators ready at the ballast tank entrance for emergencies; and</p> <p>.7 always carry devices to enable communication from inside the tank to people outside in emergency situations.</p>	
11.4.11	The Group recommended that adequate respiratory protective devices should be used during ballast tank inspection to prevent unacceptable long-term risks to the crew performing inspections.	When entering the ballast tank, ship crew must strictly observe the hazard prevention rules described in section 1.1.9 above. In addition, whenever doing so, they should wear appropriate PPE, such as safety helmets, safety belt, long-sleeve work clothes, protective goggles, chemical-resistant rubber gloves, rubber boots, rubber clothes and a protective mask to prevent the inhalation of halogen gases and organic gases.	<i>The Group noted the response</i>
11.4.12	The Group noted that the PEC/PNEC ratios for bromate and chlorate exceeded 1 in both the harbour and the near sea scenarios. The Group recommended that the applicant take care of this potentially hazardous situation, e.g. by appropriate mitigation measures in any future application for Final Approval.	<p>The reason why PEC/PNEC ratios of bromate and chlorate were higher than 1 was that the assessments were made with a chlorine concentration inside the ballast piping of approximately 30 mg/L as Cl₂. Moreover, the biocide had been stored at a high temperature before use in the test. The improvements for those factors were presented in that application, too.</p> <p>In this application for Final Approval, the chlorine concentration inside the ballast piping of the land-based test equipment was kept below 20 mg/L for improvement. All the tests, including the analysis of by-products and toxicity tests on aquatic organisms, were performed under that condition with the collected test waters. The storage of the biocide was also improved so that the temperature was kept at 25°C or below using a chiller. Consequently, the PEC/PNEC ratios of bromate and chlorate remained below 1, which</p>	<i>The Group was satisfied with the response</i>

Section in MEPC 66/2/10, annex 4	Group's Recommendation	Applicant's response	Group's reaction
		indicates that the temperature control of the biocide is effective. The ratios for all the other detected Relevant Chemicals were also below 1 and the impact on the environment was proven not to be significant. The details of the results are described in section 8.3.	

4.1 During the GESAMP-BWWG meeting, the Group posed 18 questions to the applicant. The Group's questions (in **bold text**), the applicant's responses (in plain text) and the reactions of the Group (in *italic text*) are noted below, in numerical order of the individual questions.

Question 1

Please outline for the substance sodium hypochlorite the specific features of the BWMS risk management system that will address the safety advice given by the IMDG Code and International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (IBC Code). The Group is of the opinion that this kind of information should be included in the Operating Manual.

Response 1

The IMDG Code and IBC Code characterizations of sodium hypochlorite are Class 8 (corrosive substance) and 196, respectively. In the IBC Code, sodium hypochlorite is regulated as follows. Therefore, these will be added in the operation manual.

Pollution Category	: Y
Hazards	: S/P
Ship type	: 3
Tank type	: 2 (integral tank) G (gravity tank)
Tank vent	: controlled venting
Tank environmental control	: No
Gauging	: R (restricted gauging)
Vapour detection	: No (indicates no special requirements under this code)
Fire protection	: No (indicates no special requirements under this code)
Emergency equipment	: No (indicates no special requirements under this code)

Group's reaction

The Group noted the response.

Question 2

Section 4.3 of appendix F (Manual of KURITA™ BWMS) in the confidential dossier discusses the storage of the Preparation (biocide solution). Please indicate how the chilling of the product is to be physically achieved along with any safety implications.

Response 2

Sodium hypochlorite solution is circulated between its storage tank (T-11) and a heat exchanger (HE-11) by a biocide circulating pump (P-12A/B) and cooled to below 25°C by heat exchange with cold water prepared by a chiller (M-16). Chiller capacity is determined assuming an average room temperature of 55°C, an average cold water temperature of 15°C, heat release extent (heat loss constant) of the biocide tank (T-11) and thermal conductivity of relevant materials. Since parts of biocide circulating pump (P-12A/B) and heat exchanger (HE-11) which contact with biocide solution consist of titanium, which has enough corrosion resistance, leakage of biocide solution due to corrosion is avoided. A protective dike is provided under the piping for biocide circulation, the biocide circulating pump (P-12A/B) and the biocide tank (T-11).

Group's reaction

The Group noted the response.

Question 3

In Section 4.4.3 of the Confidential Assessment Report_E and page 35 of appendix F, it is stated that the TRO2 analyser will initially alarm if the TRO concentration of the discharged water detected is > 0.1 mg/l with the result that the neutralizer dosage is appropriately increased. Once this occurs, it is stated that there are 4 subsequent alarms before system shutdown. During this sequence, please indicate the time period from the start of the first alarm and the interval between the successive alarms before the system shuts down as per the confidential assessment. During these alarms, what action is being taken by the system? Further to this, there is a similar alarm sequence when TRO2 detects >0.2 mg/l TRO in the discharged water, with the system finally being shut down as result of five successive alarms. Could the applicant please clarify how the operator would interpret the difference between these two alarm functions?

Response 3

First of all, the concept of alarm to secure the MADC for deballasting process is explained. In the KURITA™ BWMS, 1.6 times of chemical equivalent of neutralizer is added and TRO of the discharged water can be lowered below detection limit (0.05 mg/L as Cl₂). The alarm system is provided to avoid discharged water with high TRO in the beginning of the deballasting process or in case of abrupt changes of ballast water flow rate. Specifically, the alarm is triggered when TRO of discharged water exceeds not only 0.2 mg/L as Cl₂ but 0.1 mg/L as Cl₂. The alarm for 0.1 mg/L as Cl₂ can help to find possible trouble of system early.

TRO measurement is carried out every 60 seconds. When TRO of discharged water exceeds 0.1 mg/L as Cl₂, an alarm will beep for 20 seconds. Therefore, the interval of the successive alarms is 40 seconds. When TRO higher than 0.1 mg/L as Cl₂ is detected five successive times, system will shut down with alarm which continues until the alarm reset button is pressed.

When TRO of discharged water exceeds 0.2 mg/L as Cl₂, an alarm will beep also for 20 seconds. When TRO higher than 0.2 mg/L as Cl₂ is detected three successive

times, system will shut down with alarm which continues until alarm reset button is pressed.

During these alarms, except after the shutdown, neutralizer dosage is increased by the system automatically. Although the alarm sounds the same for TRO concentration higher than 0.1 mg/L and that higher than 0.2 mg/L, crews can know whether TRO exceeds 0.1 mg/L or 0.2 mg/L as Cl_2 for alarm by checking the message displayed at the control panel.

Group's reaction

The Group was satisfied with the response.

Question 4

With reference to section 3.4 of appendix F and section 4.2.1.2 of the non-confidential dossier, please define 'good ventilation during storage' and provide more detail concerning the systems that will be employed to remove gasses from the area around the Preparation (biocide solution) storage tank.

Response 4

Biocide solution storage tank (T-11) doubles as biocide solution supply tank in which biocide solution is stored on a ship. Pipe for ventilation is attached to the upper surface of the tank (T-11) and extended to a deck to discharge gases from the tank. The outlet at the deck is located at an adequate place to avoid corrosion of a ship body and exposure to crews. Since gases such as oxygen are liberated from self-decomposition of biocide, gases inside the tank can be discharged through the pipe by pressure without a fan.

Group's reaction

The Group noted the response.

Question 5

Kindly explain the relevance of the 200 mile exclusive economic zone when performing inspections as outlined in section 5.2.1 of appendix F.

Response 5

Inspection before the discharge of ballast water makes it possible for maintenance staff of Kurita Water Industries to prepare necessary equipment and/or chemicals according to problems found in the inspection. As a result, necessary measures for ship can be done at ports. Performing at the 200 mile exclusive economic zone is described as an example for ship crews to have time to spare for the inspection.

Group's reaction

The Group noted the response.

Question 6

Please describe the process for replacing the Preparation (biocide solution) storage tank contents should they become unusable through decomposition or contamination.

Response 6

When biocide solution in the tank is judged not to be used as a result of chlorine concentration checking described as response 17 or by contamination, such information is sent to Kurita staff from ship crews for Kurita staff to prepare necessary equipment and/or chemicals. Replacement of unusable biocide solution is carried out as follows at a port ship enters. Works including preparation of equipment can be done by Kurita staff.

- a. Biocide solution waste pump is carried on a ship and connected to the drain valve (V-124) of the biocide storage tank (T-11) by Kurita staff.
- b. Discharge outlet of the biocide solution waste pump is connected to an inlet of a tank truck for recovery of unusable biocide solution.
- c. Unusable biocide solution is transferred to the tank truck by the biocide solution waste pump.
- d. After removing the unusable biocide solution from the tank (T-11), all equipment for this operation are taken out from a ship.
- e. New biocide solution is loaded to a ship according to section 4.2 of the operation manual.

Group's reaction

The Group was satisfied with the response.

Question 7

At the Basic Approval evaluation the Group had recommended to fully automate the operation of the neutralizer and to fully describe the safety measures for the handling and storage of the neutralizer on board in the Operations Manual of the BWMS (recommendation 11.4.6). Since the crew has to perform several activities with the neutralizer this results in unit operations with a certain risk for the crew. The Group is of the opinion that the current wording of the precautions proposed are not sufficiently detailed to warrant against potential risks. Please comment.

Response 7

For the recommendation from the Group, Kurita automated the deballasting process except several steps to prepare the neutralization solution and procedures for these steps were described in detail. We will continue to revise the wording of the precautions in the operation manual to warrant against potential risks. Necessary amount of neutralizer, sodium sulfite, for 100,000 m³ of ballast water is 5.7 t, assuming 1.6 times equivalent of neutralizer for TRO of 20 mg/L as Cl₂.

Using 1,000 L of flexible container, since neutralizer procedure can be finished with three times of operation, associated risks are judged as usual level.

Group's reaction

The Group noted the response.

Question 8

In the operating manual, very limited information is provided about the handling and dissolution of the neutralizer (see section neutralizer dissolver tank on page 9). The Group noted that the applicant presented additional information in his response to recommendation 11.4.6. The Group recognized that the Operation Manual was not updated with this additional information. Please comment.

Response 8

In the operation manual, information for the handling and dissolution of the neutralizer was provided such as information for safety of neutralizer at chapter 3.4.2, that for loading at 4.4, that for storage at 4.5 and that for dissolution at 5.2.2. As mentioned above, we will continue to revise the wording to warrant against potential risks. Handling of neutralizer for 100,000 m³ of ballast water can be done with three times operation using 1,000 L of flexible container of neutralizer as described above. Therefore, associated risks are judged as usual level.

Group's reaction

The Group noted the response.

Question 9

The Group noted that 'to guarantee neutralization of the TROs in the treated ballast water to be discharged, the dosage of neutralizer is set to 1.6 times the quantity required for their neutralization'. Also the Group noted that the BWMS uses 'neutralizer dissolving tank to prepare a 10% solution of the granular neutralizer'. According to the experience of the Group, the volume of neutralizer solution needed appears to be very high for this BWMS. Please comment.

Response 9

The neutralizer dose of 1.6 times equivalent is experimentally determined to ensure the MADC (< 0.2 mg/L as Cl₂), and concentration of 10% is typical for sodium sulfite. Since our biocide dosage is as high as 20 mg/L as Cl₂ to eliminate filters, required volume of neutralizer solution is high compared to conventional BWMSs. Our simple system without filter, however, is getting attention from customers.

Group's reaction

The Group noted the response.

Question 10

The Group noted that data was not presented for fresh water toxicity tests with vertebrate or invertebrate species. The Group is of the opinion that fresh water WET testing should also be performed for all trophic levels in accordance with the GESAMP-BWWG Methodology (BWM.2/Circ.13/Rev.1). Are there plans to follow up with fresh water toxicity tests? Please note that the applicant stated in QAPP for land-based test (APP-B-1 in the confidential dossier) that acute and chronic tests on three types of aquatic organisms using neutralized fresh water will be conducted (referred to 2-1 (3) on page 5 and 2-7 (3) on page 10).

Response 10

Since toxicity testing for Final Approval should be performed as part of the land-based type approval process using the treated ballast water discharge (G9 5.2.1.2), it was carried out using seawater and brackish water according to the Guidelines (G8), annex, Part 2, paragraph 2.3.18, which describes that at least two sets of tests cycles should be conducted, each with a different salinity range. On the other hand, according to the GESAMP-BWWG's comment (MEPC 66/2/10, annex 4, paragraph 11.4.7), WET test was carried out for fresh water. This test was performed to check the residual toxicity described in the Methodology (BWM.2/Circ.13/Rev.1) using only algae which is most sensitive among all trophic levels according to the GESAMP-BWWG Fourth Stocktaking Workshop (MEPC 65/2/8) describing that "Algae are generally considered as the most sensitive species in ecotoxicity tests with treated ballast water." In the QAPP (APP-B-1) we planned testing using three kinds of water (seawater, brackish water and fresh water) and three kinds of aquatic organisms. From above consideration, testing is not planned to follow up with fresh water toxicity.

Group's reaction

The Group noted the response.

Question 11

The applicant states in paragraph 8.2.2.3 of confidential dossier that 'the ballast water treated under seawater and brackish water requirements was tested for its acute and chronic toxicity to three kinds of aquatic organisms: algae, crustaceans and fish, while the ballast water treated under fresh water requirements was tested for growth inhibition of algae'. Please provide scientific background to support the statement mentioned above.

Response 11

Since toxicity testing for Final Approval should be performed as part of the land-based type approval process using the treated ballast water discharge (G9 5.2.1.2), it was carried out using seawater and brackish water according to the Guidelines (G8), annex, Part 2, paragraph 2.3.18 which describes that at least two sets of tests cycles should be conducted, each with a different salinity range. On the other hand, according to the GESAMP-BWMG's comment (MEPC 66/2/10, annex 4, paragraph 11.4.7), WET test was carried out for fresh water. This test was performed to check the residual toxicity described in the Methodology (BWM.2/Circ.13/Rev.1) using only algae which is the most sensitive among all trophic levels according to

the GESAMP-BWWG Fourth Stocktaking Workshop (MEPC 65/2/8) describing that "Algae are generally considered as the most sensitive species in ecotoxicity tests with treated ballast water."

Group's reaction

The Group noted the response.

Question 12

In the human health risk assessment, DMEL evaluation of five carcinogenic substances indicated a potential cancer risk during ballast water sampling, ballast tank cleaning, and/or tank inspection. The highest RCR is 42 (for tribromomethane in the tank cleaning scenario), which requires a reduction of exposure by at least 98%. The applicant estimates that a reduction of exposure to 2% or lower of unprotected working can be achieved using PPE. Please provide some details underlying this estimation, e.g. specifications of the effectiveness of individual risk reduction measures?

Response 12

Exposure to tribromomethane in the tank cleaning scenario (table 7.7 of the confidential dossier) consists of dermal exposure and inhalation one. Dermal exposure of 2.88E-04 (mg/kg bw/d) is negligible compared with that of inhalation (3.24E-01 mg/kg bw/d). For example, according to the information of the manufacturing company (KOKEN Ltd.), the gas mask KGC-1M including of active carbon can absorb tribromomethane 99.9% or more.

Group's reaction

The Group noted the response.

Question 13

The Group noted that for the measurement of TRO, three times dilution with on board tap water is implemented. Even using this tap water the natural degradation rate of TRO during the mixing process could be under-estimated. However the applicant did not provide any technical description of how this will be achieved automatically. Please comment.

Response 13

In reports and the operation manual for Final Approval, fresh water is used to dilute samples for TRO measurements. Since fresh water provided on a ship generally does not include organic compounds to help degradation of TRO and suspended solids can be removed by the strainer located in front of the TRO meter, it is judged that use of fresh water as a dilution liquid does not effect substantially on TRO measurement. Duration of contact with fresh water required to measure after dilution is about 30 seconds, which is short enough to avoid TRO degradation. It is also confirmed that there is no difference between the TRO value detected by the TRO meter using fresh water above and the TRO value detected by DPD method using pure water.

Group's reaction

The Group noted the response.

Question 14

The applicant stated in 'QAPP for production of Chlorate and Bromate during Ballast water Treatment by Sodium Hypochlorite' (APP-B-4 of the confidential dossier) that measurements and analysis would be performed including:

- .1 chemical analyses for various Active Substances (sodium hypochlorite solution);**
- .2 increase of chlorate during the storage time (9 days) under different temperatures; and**
- .3 impacts of phosphate contents on the production of chlorate during the storage time.**

However, appendix J, titled 'production of Chlorate and Bromate during Ballast water Treatment', contains only the results of .1 mentioned above. Please provide the full report including the results of .2 and .3 mentioned above.

Response 14

Regarding .2, the test report of "increase of chlorate during the storage time under different temperatures" is attached as Report of Chlorate and Bromate Production during Ballast Water Treatment by Sodium hypochlorite, Document No. YEN7520-R121018, indicating that self-decomposition of sodium hypochlorite in biocide solution is successfully suppressed by storing it below 25°C.

As for ".3 impacts of phosphate contents on the production of chlorate during the storage time", the tests were not carried out as was described in chapter 2.3 of APP-B-4, because the influence of phosphate on decomposition of sodium hypochlorite is easily estimated by the difference of the available chlorine concentrations between biocide solutions with and without phosphate.

Group's reaction

The Group noted the response.

Question 15

The applicant stated in page 14 of appendix E that the chlorate in treated ballast water derives from self-decomposition of Preparation during its storage. The applicant proposed to maintain the temperature of Active Substance as < 25°C during its storage by using a chiller.

The applicant also stated that during the land-based test, the temperature of the storage tank was maintained at 15°C. However, the group also recognized that 790 µg/L of the chlorate was observed during this test. It seems that the effect of the chilling is unclear. Please comment.

Response 15

Chlorate is produced by self-decomposition of sodium hypochlorite, and its reaction rate becomes slower as temperature is lower. As described in APP-J 3-1-1, PEC/PNEC of chlorate can be lower than 1 until concentration of sodium hypochlorite in biocide solution drops to 7.3% as Cl_2 . This means Cl_2 of 6.7% decomposed if the initial Cl_2 concentration is assumed 14%. Because about 3,500 mgs of chlorate are produced for every 1 g of available chlorine decomposes, 6.7% reduction of Cl_2 will produce 23,500 mg/L of chlorate. Therefore, when biocide solution of 12% Cl_2 is added to the ballast water to make Cl_2 concentration of 20 mg/L, the chlorate concentration will be reduced from 23,500 to 3.9 mg/L. This value will result in about one for PEC/PNEC of chlorate in harbour.

Chlorate in the treated ballast water tested for Basic Approval without temperature control increased to 8,400 $\mu\text{g/L}$ during 5 months with increasing rate of 1,680 $\mu\text{g/L/month}$ (figure 5, of the confidential dossier for Basic Approval). On the other hand, at the land-based test chlorate concentration at 2 months storage at 15°C was 790 $\mu\text{g/L}$ (table 15, App-E) indicating the increasing rate of 395 $\mu\text{g/L/month}$. When comparing those values, 1,680 $\mu\text{g/L/month}$ for chlorate increase without temperature control and 395 $\mu\text{g/L/month}$ for that with temperature control at 15°C, the effect of chilling on the inhibition of chlorate formation is very clear.

Group's reaction

The Group noted the response.

Question 16

The applicant stated in appendix-J that 'the allowable storage period of Active Substance is five months at 25°C and eighteen months at 15°C'. This statement is not consistent with the observation in Question 15. Please provide scientific clarification to establish these storage times. Also, provide the actual tank storage time that was in place when the applicant observed the chlorate concentration of 790 $\mu\text{g/L}$ mentioned above.

Response 16

As described in APP-J 3-1-1, PEC/PNEC of chlorate can be lower than 1 until concentration of sodium hypochlorite in biocide solution drops to 7.3% from the initial concentration of 14% as Cl_2 . This means 6.7% of Cl_2 are decomposed. For every 1g of available chlorine decomposes, about 3,500 mgs of chlorate are produced, so 6.7% decomposition will produce 23,500 mg/L of chlorate. Therefore, when biocide solutions of 12% Cl_2 are added to the ballast water to make Cl_2 concentration of 20 mg/L, the chlorate concentration will be reduced from 23,500 to 3.9 mg/L, resulting in PEC/PNEC of chlorate of about 1.

The rate of chlorine decomposition is shown in the figure 1 of the Document number YEN7520-R121018, Report of Chlorate and Bromate Production during Ballast Water Treatment by Sodium hypochlorite. At 25°C, 1.19% of Cl_2 are decomposed for one month, and 0.37%, at 15°C.

The allowable storage period of biocide solutions was established from decreasing rate of sodium hypochlorite as Cl_2 of 0.37%/month at 15°C and 1.19%/month at 25°C. It will take 18 months at 15°C and 5 months at 25°C for sodium hypochlorite

concentration decrease to 7.3% from 14% as Cl_2 . Experimental results for chlorine decomposition from figure 1 of the Document No. YEN7520-R121018, Report of Chlorate and Bromate Production during Ballast Water Treatment by Sodium hypochlorite is attached below as figure 1. Storage period of sodium hypochlorite for which 790 $\mu\text{g/L}$ of chlorate was detected was 2 months.

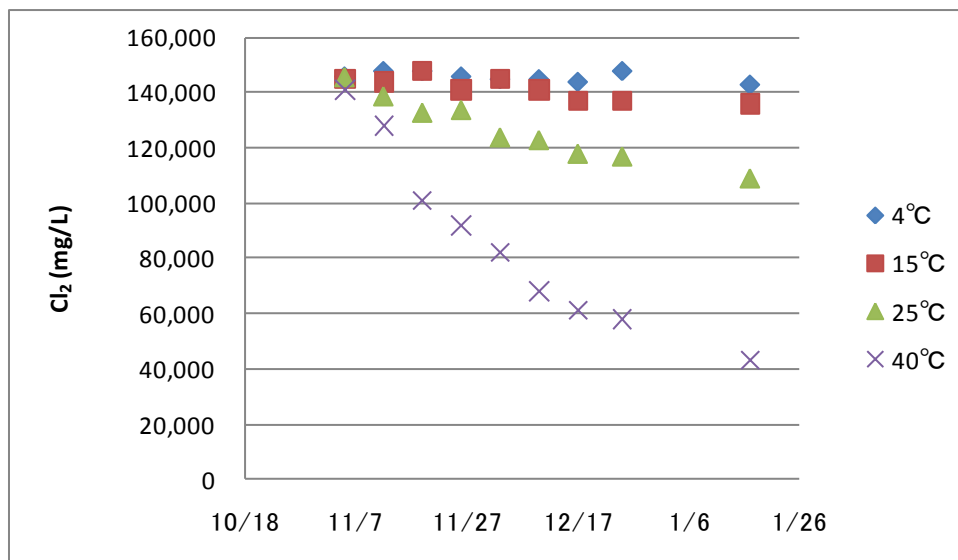


Figure: Chlorine decomposition during storage

Group's reaction

The Group noted the response.

Question 17

During the Basic Approval evaluation, the applicant stated in their response as follows (refer to Response 5 of MEPC 66/2/10, annex 5, paragraph 4.1):

We present to customer the allowable storage period at the storage temperature by measuring the concentration of effective chlorine at the delivery time of sodium hypochlorite. If the allowable storage period is close or exceeded, the effective chlorine concentration is measured by the DPD method manually. It can be used when the effective chlorine concentration is sufficiently-higher than the case for PEC/PNEC below 1, if not, it should not be used.

However, this procedure to ensure chlorine concentration was not implemented in the operating manual. Please comment.

Response 17

As described in the Final Approval confidential dossier 4.2.1, 'the allowable storage period is roughly estimated for five months at 25°C and eighteen months at 15°C. As described in APP-J, chlorate concentrations in the biocide solution can be estimated by measuring the concentration of sodium hypochlorite, and PEC/PNEC of chlorate can be lower than 1 until the concentration of sodium hypochlorite in the

biocide solution reaches at 7.3% as Cl_2 . But in the actual situation, sodium hypochlorite solution cannot always be delivered at 14% concentration. Therefore, allowable storage period of particular biocide solution varies depending on terms and conditions of storage of the biocide solution. Therefore, the crew or the operator of the BWMS has to know allowable period still remains to be stored at the storage temperature. This can be done by measuring the concentration of effective chlorine of the biocide solution. And the effective chlorine concentration starts to be measured by the crew before one month of the expiring date by the DPD method manually. Storage period of about five months can be possible at 25°C. And re-measurement is necessary to be carried out for confirmation. DPD analysis procedure of sodium hypochlorite is as follows and will be added to the operation manual:

- .1 Open the sampling valve of a biocide tank and sample 100 ml of biocide to the 1 L plastic beaker. At this time, PPE, such as safe glasses and latex gloves, are worn.



WARNING

- When handling chemicals, always wear protector, such as long sleeved working clothes, protective goggles, chemical resistant rubber gloves, rubber boots, rubber aprons and a mask that absorb halogen and organic gases.
- Make sure of adequate ventilation when handling chemicals.
- In the event chemicals are in contact with the body, or when toxic gas, such as chlorine gas has been inhaled, refer to "8.4 Biocide MSDS" attached to this manual and take appropriate measures.

- .2 Add 9 ml pure water to each five conical tubes of 15 ml using the 10 ml auto pipette.
- .3 Add 1 ml biocide to 9 ml pure water in 15 ml conical tubes using the 1 ml auto pipette and agitates up and down by hand with cover.
- .4 Dilute the biocide by serial dilution method and make it 1/100,000 finally.
- .5 Analyse the chloride concentration of biocide diluted 1/100,000 according to operation manual of Chapter 8.2, DPD analysis manual.
- .6 The analytical value should be multiplied with 100,000 and the resulting value is the available chlorine concentration of biocide.

Group's reaction

The Group noted the response.

Question 18

The Group noted that the Active Substance sodium hypochlorite is carried on board as a 12% solution and several steps during supply and storage will require crew handling, i.e. opening and closing outlet valves, with possibility of leakage. The Group would like to be informed about the foreseen maximum quantity/volume of the biocide solution needed to operate the BWMS.

Response 18

The maximum capacity of ballast water for the KURITA™ BWMS is expected as 100,000 m³. Necessary amount of biocide solution for ship with 100,000 m³ of ballast water is calculated as 20 m³. Since the maximum packaging of biocide solution is 20 m³ of container, the above maximum amount of biocide solution can be loaded at once. Therefore, work of opening and closing outlet valves is also one time.

Group's reaction

The Group was satisfied with the response.

5 HAZARD PROFILE AND EXPOSURE DATA FOR RELEVANT CHEMICALS**5.1 Predicted No Effect Concentrations (PNEC)**

5.1.1 The Group has defined the Relevant Chemicals for which a further risk assessment has to be carried out (see table 4). The Group has used the data available in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water for all substances except chlorate where the data provided by the applicant had been used. The PNECs of the Relevant Chemicals are shown in table 6.

Table 6: PNEC values of Relevant Chemicals

Chemical name	Harbour			Near sea		
	AF	PNEC (µg/L)	Rule No.	AF	PNEC (µg/L)	Rule No.
Bromate		1.3E+0			1.3E+1	
Bromochloroacetic acid		1.6E+1			1.6E+1	
Chlorate*	1000	1.1E+2	2	100	1.1E+3	2
Dibromoacetic acid		6.9E+0			6.9E+1	
Dibromochloroacetic acid		6.0E+1			6.0E+1	
Dibromochloromethane		6.3E+0			2.7E+2	
Dichloroacetic acid		2.3E+0			2.3E+1	
Dichlorobromoacetic acid		6.0E+1			6.0E+1	
Dichlorobromomethane		7.8E+1			2.8E+2	
Formaldehyde		5.8E+0			5.8E+1	
Monobromoacetic acid		1.6E+1			1.6E+1	
Monochloroacetic acid		5.8E-1			5.8E-1	
Tribromoacetic acid		6.0E+1			6.0E+1	
Tribromomethane		9.6E+1			2.9E+2	
Trichloroacetic acid		6.0E+1			6.0E+1	
Trichloromethane		1.5E+2			1.5E+2	

* Values from the applicant are being used.

5.2 Derived No Effect Levels (DNEL) and/or Derived Minimum Effect Level (DMEL)

5.2.1 The Group noted the CMR properties associated with the selected Relevant Chemicals (see table 7), and the DNEL values to be used in the human risk assessment (see table 8).

Table 7: CMR properties for selected Relevant Chemicals

	Carcinogenic	Mutagenic	Reprotoxicity	CMR
Bromate	1	1	0	1
Bromochloroacetic acid	1	0	1	1
Chlorate	0	0	0	0
Dibromoacetic acid	1	1	0	1
Dibromochloroacetic acid	0	0	0	0
Dibromochloromethane	1	0	0	1
Dichloroacetic acid	1	0	0	1
Dichlorobromoacetic acid	0	0	0	0
Dichlorobromomethane	1	0	0	1
Formaldehyde	0	0	0	0
Monobromoacetic acid	0	0	0	0
Monochloroacetic acid	0	0	0	0
Tribromoacetic acid	0	0	0	0
Tribromomethane	1	0	0	1
Trichloroacetic acid	0	0	0	0
Trichloromethane	0	0	1	1

5.2.2 Based on these results, the Group concluded that some chemicals are CMR substances.

Table 8: DNELs and DMELs to be used in the risk assessment for humans

Chemical	DNEL (mg/kg bw/d) Crew	DNEL (µg/kg bw/d) General public	DMEL (µg/kg bw/d)
Bromate	2.2E-2	1.1E+1	1.1E-1
Bromochloroacetic acid	1.2E+0	6.2E+2	NA
Chlorate*	5.2E+1	6.7E+2	NA
Dibromoacetic acid	7.2E-2	3.6E+1	1.3E-1
Dibromochloroacetic acid	3.0E-1	1.5E+2	NA
Dibromochloromethane	2.1E-1	1.1E+2	1.5E+0
Dichloroacetic acid	1.2E-1	6.0E+1	1.7E+0
Dichlorobromoacetic acid	8.6E-1	4.3E+2	NA
Dichlorobromomethane	4.0E-2	2.0E+1	2.4E+0
Formaldehyde	2.0E-1	1.0E+2	NA
Monobromoacetic acid	7.0E-2	3.5E+1	NA
Monochloroacetic acid	7.0E-2	3.5E+1	NA
Tribromoacetic acid	8.6E-1	4.3E+2	NA
Tribromomethane	1.8E-1	9.0E+1	7.7E+0
Trichloroacetic acid	8.6E-1	4.3E+2	NA
Trichloromethane	7.8E-2	2.6E+1	NA

* Values from the applicant are being used.
NA = not available.

5.3 Predicted Environmental Concentrations (PEC)

5.3.1 The predicted environmental concentrations (PEC) of chemicals are estimated using the Marine Anti-foulant Model to Predict Environmental Concentrations (MAMPEC version 3.0 with the GESAMP-BWWG emission scenario). For the calculation of the PEC, the concentrations mentioned in table 3 in section 3 were used to establish the PEC in the harbour and in the near sea situation. The results are shown in table 9.

Table 9: PEC from MAMPEC modelling results from the GESAMP-BWWG Model Harbour for the harbour and the near sea scenario

Chemical name	PEC (µg/L)	
	Harbour	Near sea
Bromate	2.5E+1	2.0E+2
Bromochloroacetic acid	1.9E-1	1.5E+0
Chlorate	2.1E+1	1.7E+2
Dibromoacetic acid	2.6E+0	2.1E+1
Dibromochloroacetic acid	3.2E-1	2.5E+0
Dibromochloromethane	2.8E-1	6.1E+0
Dichloroacetic acid	4.9E-1	3.8E+0
Dichlorobromoacetic acid	2.7E-1	2.1E+0
Dichlorobromomethane	8.6E-2	2.2E+0
Formaldehyde	1.6E-1	1.3E+0
Monobromoacetic acid	2.7E-1	2.1E+0
Monochloroacetic acid	5.4E-2	4.2E-1
Tribromoacetic acid	4.0E+0	3.2E+1
Tribromomethane	9.6E+0	1.8E+2
Trichloroacetic acid	5.4E-1	4.2E+0
Trichloromethane	1.2E-1	3.7E+0

5.4 Concentration of Relevant Chemicals in the atmosphere

5.4.1 Once the concentrations of chemicals in the ballast tank, and the concentration of chemicals after discharge, that is the predicted environmental concentration (PEC) values as calculated by MAMPEC, have been established, the corresponding concentration of the chemicals evaporating into the air may be calculated (see table 10).

Table 10: Resulting concentrations to be used in the risk assessment for humans

Chemical	Crew		General public	
	Concentration in tank (µg/L)	Concentration in air (mg/m ³)	Concentration MAMPEC (µg/L)	Concentration in air (mg/m ³)
Bromate	9.2E+2	3.7E-4	2.47E+1	1.0E-6
Bromochloroacetic acid	7.0E+0	4.5E-7	1.9E-1	1.2E-9
Chlorate	7.9E+2	1.7E-10	2.1E+1	4.4E-13
Dibromoacetic acid	9.7E+1	1.8E-6	2.6E+0	4.7E-9
Dibromchloroacetic acid	1.2E+1	1.3E-7	3.2E-1	3.4E-10
Dibromochloromethane	3.0E+1	1.2E-1	2.75E-1	1.1E-4
Dichloroacetic acid	1.8E+1	6.2E-7	4.85E-1	1.7E-9
Dichlorobromoacetic acid	1.0E+1	3.2E-7	2.7E-1	8.7E-10
Dichlorobromomethane	1.1E+1	9.5E-2	8.58E-2	7.4E-5
Formaldehyde	6.0E+0	8.2E-6	1.6E-1	2.2E-8
Monobromoacetic acid	1.0E+1	2.7E-7	2.7E-1	7.2E-10
Monochloroacetic acid	2.0E+0	7.6E-8	5.4E-2	2.0E-10
Tribromoacetic acid	1.5E+2	2.1E-6	4.0E+0	5.5E-9
Tribromomethane	8.9E+2	2.0E+0	9.6E+0	2.1E-3
Trichloroacetic acid	2.0E+1	1.4E-6	5.4E-1	3.6E-9
Trichloromethane	1.8E+1	2.7E-1	1.2E-1	1.8E-4

6 WET TESTS

6.1 The Group noted that the results of WET tests on algae, crustacean and fish performed by the applicant with 100% treated ballast water after neutralization for both seawater (33 PSU) and brackish water (20 PSU) were presented.

6.2 The Group also noted that the applicant did not submit data on fresh water (0.3 PSU) WET tests for species from all three trophic levels, but only for algae.

6.3 The Group noted that the results of the WET tests were summarized as in Table 11.

Table 11: Summary of WET tests of treated ballast water after neutralization to test organisms

Test	Test organism	Salinity (PSU)	End Points (%)			References/ guidelines
			NOEC	LOEC	L(E)C ₅₀	
Algal growth inhibition	<i>Skeletonema costatum</i>	33	100	-	>100	ISO 10253 (2006)
		20	100	-	>100	
	<i>Desmodesmus subspicatus</i>	0.3	100	-	>100	OECD 201 (2011)
Acute crustacean	<i>Hyale barbicornis</i>	33	100	-	>100	US EPA OPPTS 850.1020 (1996)
		20	100	-	>100	
Acute fish	<i>Oryzias javanicus</i>	33	100	-	>100	OECD 203 (1992)
		20	100	-	>100	
Chronic crustacean	<i>Hyale barbicornis</i>	33	100	>100	-	Añasco et al. (2008)
		20	100	>100	-	
Chronic fish	<i>Oryzias javanicus</i>	33	100	>100	-	OECD No. 215 (2000)
		20	100	>100	-	

6.4 The Group noted that no toxicity was shown on any test organisms from the results of WET test with test water from the BWMS.

6.5 The Group concluded that the results of WET tests indicate that there should not be unacceptable effects to the environment.

7 RISKS TO SHIP SAFETY

7.1 The Group noted that specific countermeasures are to be employed in this BWMS to deal with envisaged safety issues during the ballast water treatment. These have been outlined in the operating manual presented for Final Approval. The Group observed that more comprehensive safety and operating manuals would be required prior to the issuance of a Type Approval Certificate by the administration.

7.2 Given the nature of the Active Substance and its proposed storage on board, the Group recommended that there was a need by the applicant to consider and incorporate elements of the appropriate safety advice given by the IMDG Code and International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (IBC Code).

7.3 The Group noted that a full report of corrosion tests had been included in the application for Final Approval and that no enhanced corrosion had been detected.

8 RISKS TO THE CREW

8.1 The Group made a risk assessment taking into account the following scenarios from the Methodology in this case:

- .1 delivery, loading, mixing or adding chemicals to the BWMS;
- .2 ballast water sampling;
- .3 periodic cleaning of ballast tanks;
- .4 ballast tank inspections; and
- .5 normal work on deck unrelated to any of the above.

Delivery, loading, mixing or adding chemicals to the BWMS

8.2 The Group noted that this BWMS requires loading of the Preparation to the storage tank, during which dermal contact to the Active Substance might occur due to spillage. The applicant carried out a risk assessment for the acute systemic toxicity based on this scenario (see table 12).

Table 12: Crew, scenario: delivery and loading of Preparation

Chemical	AS concentration	Dermal exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
NaOCl	12%	2.4E+0	9.6	0.25

8.3 The Group recognized that as the RCR is below 1, dermal exposure of workers while loading the Preparation will not pose an unacceptable risk of acute systemic effects.

8.4 However, the Group also noted that the acute toxicity of the Active Substance is primarily characterized by its corrosive effects on the skin and eyes. Therefore, the Group recommended that adequate skin and eye protection should be used during loading of the Preparation.

Ballast water sampling

8.5 The Group noted that the resulting dose from the aggregated exposure from ballast water sampling, when compared with a DNEL value, does not lead to an RCR above 1 for any substance (see table 13).

Table 13: Port State control, scenario: ballast water sampling (2 hours)

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	1.3E-4	1.6E-5	1.4E-4	2.2E-2	6.6E-3
Bromochloroacetic acid	9.8E-7	1.9E-8	1.0E-6	1.25E+0	8.0E-7
Chlorate	1.1E-4	6.9E-12	1.1E-4	5.2E+1	2.1E-6
Dibromoacetic acid	1.4E-5	7.3E-8	1.4E-5	7.2E-2	1.9E-4
Dibromochloroacetic acid	1.7E-6	5.2E-9	1.7E-6	3.0E-1	5.6E-6
Dibromochloromethane	4.2E-6	5.1E-3	5.1E-3	2.1E-1	2.4E-2

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Dichloroacetic acid	2.5E-6	2.6E-8	2.5E-6	1.2E-1	2.1E-5
Dichlorobromoacetic acid	1.4E-6	1.4E-8	1.4E-6	8.6E-1	1.6E-6
Dichlorobromomethane	1.5E-6	4.0E-3	4.0E-3	4.0E-2	9.9E-2
Formaldehyde	8.4E-7	3.4E-7	1.2E-6	2.0E-1	5.9E-6
Monobromoacetic acid	1.4E-6	1.1E-8	1.4E-6	7.0E-2	2.0E-5
Monochloroacetic acid	2.8E-7	3.2E-9	2.8E-7	7.0E-2	4.0E-6
Tribromoacetic acid	2.1E-5	8.6E-8	2.1E-5	8.6E-1	2.4E-5
Tribromomethane	1.2E-4	8.1E-2	8.1E-2	1.8E-1	4.5E-1
Trichloroacetic acid	2.8E-6	5.6E-8	2.9E-6	8.6E-1	3.3E-6
Trichloromethane	2.5E-6	1.1E-2	1.1E-2	7.8E-2	1.4E-1

8.6 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, ballast water sampling does not pose an unacceptable short-term risk to the port State control officers performing sampling.

8.7 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for bromate, dibromochloromethane, dichlorobromomethane and tribromomethane (see table 14).

Table 14: Port State control, scenario: ballast water sampling – DMEL approach

Chemical	Scenario "sampling" (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	1.3E-4	1.6E-5	1.4E-4	1.1E-4	1.3E+0
Dibromoacetic acid	1.4E-5	7.3E-8	1.4E-5	1.3E-4	1.0E-1
Dibromochloromethane	4.2E-6	5.1E-3	5.1E-3	1.5E-3	3.4E+0
Dichloroacetic acid	2.5E-6	2.6E-8	2.5E-6	1.7E-3	1.5E-3
Dichlorobromomethane	1.5E-6	4.0E-3	4.0E-3	2.4E-3	1.6E+0
Tribromomethane	1.2E-4	8.1E-2	8.1E-2	7.7E-3	1.1E+1

8.8 The Group noted that the largest contribution to the aggregated exposure arises from the inhalation of vapours.

8.9 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast water sampling to prevent unacceptable long-term risks to the port State control officers performing sampling.

Periodic cleaning of ballast tanks

8.10 The Group noted that the resulting dose from the aggregated exposure from ballast tank cleaning, when compared with a DNEL value, leads to an RCR above 1 for tribromomethane (see table 15).

Table 15: Crew, scenario: ballast tank cleaning (8 hours)

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	3.0E-3	6.2E-5	3.0E-3	2.2E-2	1.4E-1
Bromochloroacetic acid	2.3E-5	7.5E-8	2.3E-5	1.25E+0	1.8E-5
Chlorate	2.6E-3	2.8E-11	2.6E-3	5.2E+1	4.9E-5
Dibromoacetic acid	3.1E-4	2.9E-7	3.1E-4	7.2E-2	4.4E-3
Dibromochloroacetic acid	3.9E-5	2.1E-8	3.9E-5	3.0E-1	1.3E-4
Dibromochloromethane	9.7E-5	2.0E-2	2.0E-2	2.1E-1	9.7E-2
Dichloroacetic acid	5.8E-5	1.0E-7	5.8E-5	1.2E-1	4.9E-4
Dichlorobromoacetic acid	3.2E-5	5.4E-8	3.2E-5	8.6E-1	3.8E-5
Dichlorobromomethane	3.6E-5	1.6E-2	1.6E-2	4.0E-2	4.0E-1
Formaldehyde	1.9E-5	1.4E-6	2.1E-5	2.0E-1	1.0E-4
Monobromoacetic acid	3.2E-5	4.4E-8	3.2E-5	7.0E-2	4.6E-4
Monochloroacetic acid	6.5E-6	1.3E-8	6.5E-6	7.0E-2	9.3E-5
Tribromoacetic acid	4.8E-4	3.4E-7	4.8E-4	8.6E-1	5.6E-4
Tribromomethane	2.9E-3	3.2E-1	3.3E-1	1.8E-1	1.8E+0
Trichloroacetic acid	6.5E-5	2.2E-7	6.5E-5	8.6E-1	7.6E-5
Trichloromethane	5.8E-5	4.4E-2	4.4E-2	7.8E-2	5.7E-1

8.11 For the DNEL evaluation, the Group concluded that as the RCR was above 1 for one substance, tribromomethane, the periodic cleaning of ballast tanks could pose an unacceptable risk to the crew.

8.12 The Group calculated the indicative RCR regarding potential cancer risk as detailed above and noted that the RCR was above 1 for all substances except dichloroacetic acid (see table 16).

Table 16: Crew, scenario: ballast tank cleaning – DMEL approach

Chemical	Scenario "cleaning" (mg/kg bw/d)		Aggregated exposure	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
Bromate	3.0E-3	6.2E-5	3.0E-3	1.1E-4	2.8E+1
Dibromoacetic acid	3.1E-4	2.9E-7	3.1E-4	1.3E-4	2.4E+0
Dibromochloromethane	9.7E-5	2.0E-2	2.0E-2	1.5E-3	1.4E+1
Dichloroacetic acid	5.8E-5	1.0E-7	5.8E-5	1.7E-3	3.4E-2
Dichlorobromomethane	3.6E-5	1.6E-2	1.6E-2	2.4E-3	6.6E+0
Tribromomethane	2.9E-3	3.2E-1	3.3E-1	7.7E-3	4.2E+1

8.13 The Group recognized that the scenario "Periodic cleaning of ballast tanks" is the worst-case scenario representing a potential risk to the crew by inhalation and dermal exposure. As this operation is likely to occur on a long-term basis, risk has to be mitigated by implementing operational conditions and using adequate RPE/PPE to reduce exposure as technically achievable.

8.14 The Group recommended that appropriate procedures be developed for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of the ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of the ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;
- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.

Ballast tank inspection

8.15 The Group noted that the resulting dose from the exposure from ballast tank inspection, when compared with a DNEL value, does not lead to an RCR above 1 for any substance (see table 17).

Table 17: Crew, scenario: ballast tank inspection (3 hours)

Chemical	Scenario "inspection" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	2.3E-5	2.2E-2	1.0E-3
Bromochloroacetic acid	2.8E-8	1.25E+0	2.3E-8
Chlorate	1.0E-11	5.2E+1	2.0E-13
Dibromoacetic acid	1.1E-7	7.2E-2	1.5E-6
Dibromochloroacetic acid	7.9E-9	3.0E-1	2.6E-8
Dibromochloromethane	7.6E-3	2.1E-1	3.6E-2
Dichloroacetic acid	3.9E-8	1.2E-1	3.2E-7
Dichlorobromoacetic acid	2.0E-8	8.6E-1	2.4E-8
Dichlorobromomethane	5.9E-3	4.0E-2	1.5E-1
Formaldehyde	5.2E-7	2.0E-1	2.6E-6
Monobromoacetic acid	1.7E-8	7.0E-2	2.4E-7
Monochloroacetic acid	4.7E-9	7.0E-2	6.8E-8
Tribromoacetic acid	1.3E-7	8.6E-1	1.5E-7
Tribromomethane	1.2E-1	1.8E-1	6.8E-1
Trichloroacetic acid	8.4E-8	8.6E-1	9.8E-8
Trichloromethane	1.7E-2	7.8E-2	2.1E-1

8.16 For the DNEL evaluation, the Group concluded that, as the RCR was below 1 for all substances, ballast tank inspection does not pose an unacceptable short-term risk to the crew performing inspection.

8.17 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was above 1 for dibromochloromethane, dichlorobromomethane and tribromomethane (see table 18).

Table 18: Crew, scenario: ballast tank inspection – DMEL approach

Chemical	Scenario "inspection" (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	2.3E-5	1.1E-4	2.1E-1
Dibromoacetic acid	1.1E-7	1.3E-4	8.5E-4
Dibromochloromethane	7.6E-3	1.5E-3	5.1E+0
Dichloroacetic acid	3.9E-8	1.7E-3	2.3E-5
Dichlorobromomethane	5.9E-3	2.4E-3	2.5E+0
Tribromomethane	1.2E-1	7.7E-3	1.6E+1

8.18 The Group noted that in this scenario only exposure from the inhalation of vapours is taken into consideration.

8.19 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast tank inspection to prevent unacceptable long-term risks to the crew performing inspection.

Normal work on deck unrelated to any of the above

8.20 The Group noted that the resulting dose from the exposure from normal work on deck, when compared with a DNEL value, does not lead to an RCR above 1 for any substance (see table 19).

Table 19: Crew, scenario: normal work on deck (1 hour)

Chemical	Scenario "normal work" (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	7.7E-7	2.2E-2	3.5E-5
Bromochloroacetic acid	9.4E-10	1.25E+0	7.5E-10
Chlorate	3.4E-13	5.2E+1	6.6E-15
Dibromoacetic acid	3.7E-9	7.2E-2	5.1E-8
Dibromochloroacetic acid	2.6E-10	3.0E-1	8.8E-10
Dibromochloromethane	2.5E-4	2.1E-1	1.2E-3
Dichloroacetic acid	1.3E-9	1.2E-1	1.1E-8
Dichlorobromoacetic acid	6.7E-10	8.6E-1	7.8E-10
Dichlorobromomethane	2.0E-4	4.0E-2	5.0E-3
Formaldehyde	1.7E-8	2.0E-1	8.6E-8
Monobromoacetic acid	5.6E-10	7.0E-2	7.9E-9
Monochloroacetic acid	1.6E-10	7.0E-2	2.2E-9
Tribromoacetic acid	4.3E-9	8.6E-1	5.0E-9
Tribromomethane	4.1E-3	1.8E-1	2.2E-2
Trichloroacetic acid	2.8E-9	8.6E-1	3.3E-9
Trichloromethane	5.6E-4	7.8E-2	7.1E-3

8.21 For the DNEL evaluation, the Group concluded that as the RCR was below 1 for all substances, normal work on deck does not pose an unacceptable short-term risk to the crew performing the work.

8.22 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk and noted that the RCR was below 1 for all substances (see table 20).

Table 20: Crew, scenario: normal work on deck – DMEL approach

Chemical	Scenario "normal work" (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Inhalation		
Bromate	7.7E-7	1.1E-4	7.0E-3
Dibromoacetic acid	3.7E-9	1.3E-4	2.8E-5
Dibromochloromethane	2.5E-4	1.5E-3	1.7E-1
Dichloroacetic acid	1.3E-9	1.7E-3	7.6E-7
Dichlorobromomethane	2.0E-4	2.4E-3	8.2E-2
Tribromomethane	4.1E-3	7.7E-3	5.3E-1

8.23 The Group concluded that, as the indicative RCR was below 1 for all substances, normal work on deck does not pose an unacceptable long-term risk to the crew performing the work.

9 RISKS TO THE GENERAL PUBLIC

9.1 The total exposure to the general public whilst swimming in the sea and consuming fish is the sum of the amount of chemical absorbed through consuming fish plus the oral intake, dermal absorption and inhalation absorption whilst swimming (see table 21).

Table 21: General public, scenario: sea bathing and consumption of seafood

Chemical	Scenario 1.1 and 1.2 (µg/kg bw/d)					DNEL (µg/kg bw/d)	RCR
	Swimming			Consumption of seafood	Aggregated exposure (µg/kg bw/d)		
	Oral	Dermal	Inhalation	Oral			
Bromate	2.6E-2	4.0E-1	5.2E-5	1.6E-2	4.4E-1	1.1E+1	4.0E-2
Bromochloroacetic acid	2.0E-4	3.1E-3	6.4E-8	1.9E-3	5.2E-3	6.3E+2	8.3E-6
Chlorate	2.2E-2	3.4E-1	2.3E-11	2.1E-1	5.7E-1	6.7E+2	8.5E-4
Dibromoacetic acid	2.7E-3	4.2E-2	2.5E-7	1.6E-3	4.6E-2	3.6E+1	1.3E-3
Dibromochloroacetic acid	3.3E-4	5.2E-3	1.8E-8	3.2E-3	8.7E-3	1.5E+2	5.8E-5
Dibromochloromethane	2.9E-4	4.4E-3	5.8E-3	6.0E-3	1.6E-2	1.1E+2	1.5E-4
Dichloroacetic acid	5.0E-4	7.8E-3	8.7E-8	6.1E-4	9.0E-3	6.0E+1	1.5E-4
Dichlorobromoacetic acid	2.8E-4	4.4E-3	4.5E-8	2.7E-3	7.3E-3	4.3E+2	1.7E-5
Dichlorobromomethane	8.9E-5	1.4E-3	3.9E-3	1.3E-3	6.6E-3	2.0E+1	3.3E-4
Formaldehyde	1.7E-4	2.6E-3	1.1E-6	1.5E-3	4.3E-3	1.0E+2	4.3E-5
Monobromoacetic acid	2.8E-4	4.4E-3	3.8E-8	8.5E-5	4.7E-3	3.5E+1	1.4E-4
Monochloroacetic acid	5.6E-5	8.7E-4	1.1E-8	1.7E-5	9.5E-4	3.5E+1	2.7E-5
Tribromoacetic acid	4.2E-3	6.5E-2	2.9E-7	3.1E-2	1.0E-1	4.3E+2	2.3E-4
Tribromomethane	1.0E-2	1.6E-1	1.1E-1	3.6E-1	6.4E-1	9.0E+1	7.1E-3
Trichloroacetic acid	5.6E-4	8.7E-3	1.9E-7	1.7E-3	1.1E-2	4.3E+2	2.6E-5
Trichloromethane	1.2E-4	1.9E-3	9.3E-3	1.7E-3	1.3E-2	2.6E+1	5.0E-4

9.2 The Group recognized that the resulting doses from the aggregated exposure for the combined scenario for the general public, when compared with DNEL, lead to an RCR below 1 for all substances.

9.3 The Group used indicative risk levels available from internationally recognized bodies to calculate the indicative RCR regarding potential cancer risk.

Table 22: General public, scenario: sea bathing and consumption of seafood – DMEL approach

Chemical	Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	Indicative RCR
Bromate	4.4E-1	1.1E-1	4.0E+0
Dibromoacetic acid	4.6E-2	1.3E-1	3.6E-1
Dibromochloromethane	1.6E-2	1.5E+0	1.1E-2
Dichloroacetic acid	9.0E-3	1.7E+0	5.3E-3
Dichlorobromomethane	6.6E-3	2.4E+0	2.8E-3
Tribromomethane	6.4E-1	7.7E+0	8.3E-2

9.4 The Group noted that the indicative RCR values show a value above 1 for one substance (bromate).

9.5 The Group concluded that there may be an elevated risk to the general public from swimming in the sea and consuming seafood, however, the Group recognized that according to the scenarios in question, the activities are taking place in the harbour where the ballast water is being discharged. The Group recognized that should the activities of the general public take place in areas more remote to the actual harbour, additional dilution of the concentrations of DBPs are to be expected.

10 RISKS TO THE ENVIRONMENT

10.1 Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T)

10.1.1 The Group noted that the applicant had made a listing of P, B and T criteria for the Relevant Chemicals found in the treated ballast water, with results being presented in table 23.

Table 23: PBT properties for selected DBP

	Persistence	Bioaccumulation	Toxicity
Bromate	N.A.*	N	N
Bromochloroacetic acid	N.A.	N	N
Chlorate	N	N	N
Dibromoacetic acid	N	N	N
Dibromochloroacetic acid	N.A.	N	N
Dibromochloromethane	N	N	N
Dichloroacetic acid	N	N	N
Dichlorobromoacetic acid	N.A.	N	N
Dichlorobromomethane	N	N	N
Formaldehyde	N.A.	N	N
Monobromoacetic acid	N	N	N
Monochloroacetic acid	N	N	N
Tribromoacetic acid	N	N	N
Tribromomethane	N	N	N
Trichloroacetic acid	N	N	N
Trichloromethane	N	N	N

* Not applicable

10.1.2 Based on these results, the Group concluded that these chemicals are not PBT-substances.

10.2 Calculation of PEC/PNEC ratios

10.2.1 The Group calculated the PEC values and used the maximum PEC concentrations to calculate the PEC/PNEC ratios.

Table 24: PEC/PNEC ratios according to the Group

Chemical name	Harbour			Near sea		
	PEC	PNEC	PEC/ PNEC	PEC	PNEC	PEC/ PNEC
	(µg/L)	(µg/L)	(-)	(µg/L)	(µg/L)	(-)
Bromate	2.5E+1	1.3E+0	2.0E+1	2.0E+2	1.3E+1	1.6E+1
Bromochloroacetic acid	1.9E-1	1.6E+1	1.2E-2	1.5E+0	1.6E+1	9.3E-2
Chlorate*	2.1E+1	1.1E+2	2.0E-1	1.7E+2	1.1E+3	1.5E-1
Dibromoacetic acid	2.6E+0	6.9E+0	3.8E-1	2.1E+1	6.9E+1	3.0E-1
Dibromochloroacetic acid	3.2E-1	6.0E+1	5.4E-3	2.5E+0	6.0E+1	4.2E-2
Dibromochloromethane	2.8E-1	6.3E+0	4.4E-2	6.1E+0	2.7E+2	2.3E-2
Dichloroacetic acid	4.8E-1	2.3E+0	2.1E-1	3.8E+0	2.3E+1	1.7E-1
Dichlorobromoacetic acid	2.7E-1	6.0E+1	4.5E-3	2.1E+0	6.0E+1	3.5E-2
Dichlorobromomethane	8.6E-2	7.8E+1	1.1E-3	2.2E+0	2.8E+2	7.9E-3
Formaldehyde	1.6E-1	5.8E+0	2.8E-2	1.3E+0	5.8E+1	2.2E-2
Monobromoacetic acid	2.7E-1	1.6E+1	1.7E-2	2.1E+0	1.6E+1	1.3E-1
Monochloroacetic acid	5.4E-2	5.8E-1	9.3E-2	4.2E-1	5.8E-1	7.3E-1
Tribromoacetic acid	4.0E+0	6.0E+1	6.7E-2	3.2E+1	6.0E+1	5.3E-1
Tribromomethane	9.6E+0	9.6E+1	1.0E-1	1.8E+2	2.9E+2	6.3E-1
Trichloroacetic acid	5.4E-1	6.0E+1	9.0E-3	4.2E+0	6.0E+1	7.1E-2
Trichloromethane	1.2E-1	1.5E+2	8.3E-4	3.7E+0	1.5E+2	2.4E-2

* Values from the applicant are being used.

10.2.2 The Group noted that the PEC/PNEC ratio for bromate exceeded 1 in both scenarios. The Group, therefore, considered that unacceptable effects on the aquatic environment may be expected.

10.2.3 The Group noted that the applicant provided an estimation of the maximum dischargeable concentration of chlorate as a transformation of the Active Substance. The Group also noted that the applicant assumed that all chlorate in the ballast water is coming from the self-decomposition of the Active Substance in the storage tank. In this estimation, the applicant proposed that a concentration of 23 g/L of chlorate should lead to a PEC/PNEC of 1. Therefore, the Group concluded the maximum concentration in the storage tank could be set to below 23 g/L.

11 CONCLUSIONS AND RECOMMENDATIONS

11.1 Risks to ship safety

11.1.1 The Group noted that initial risk mitigation measures have been proposed that can be employed with this BWMS to deal with envisaged emergency and safety problems during the ballast water treatment. These have been described and discussed above and, subject to further development of these, the Group considered that this BWMS may present no unacceptable risks to safety when the BWMS is operated as intended.

11.2 Risks to the crew and general public

11.2.1 The Group considered that the use of this BWMS, when operated as intended, should present no unacceptable risk to the health of the crew and the general public regarding the exposure to chemicals and treated ballast water. This conclusion is based on the results of the risk assessment performed and provided that the considerations and recommendations posed by the Group are addressed.

11.3 Risks to the environment

11.3.1 Having reviewed all of the environmental information submitted with this application for Final Approval, together with the risk assessment performed by the Group, the Group considered that the use of the KURITA™ BWMS will not pose any unacceptable risks for the environment when operated as intended because, although the PEC/PNEC ratios were not all below 1, the WET tests did not show any effect. In this case the Group is of the opinion that the results of the WET tests have to be considered more applicable.

11.4 Recommendation

11.4.1 Having reviewed all the data and information submitted by Japan with the application for Final Approval and the information received from the applicant during the GESAMP-BWWG meeting, the Group recommended to MEPC that Final Approval be granted to the KURITA™ Ballast Water Management System. The concerns and issues raised in this review should be addressed by the applicant to the satisfaction of the Administration prior to type approval of this BWMS. To avoid unreasonable risk to the environment, human health, property or resources, the system should be operated with the following restrictions:

- .1 **Maximum allowable dosage of Active Substance** – The maximum dose for the Active Substance should be set as follows:

TRO: 20.0 mg/L (as Cl₂);

- .2 **Maximum allowable discharge concentration of Active Substance –**
The system should ensure a maximum discharge concentration of the Active Substance TRO: < 0.2 mg/L (as Cl₂); and

- .3 **System limitations:**

Applicable range of temperature: > 4°C.

11.4.2 The Group recommended that the TRO concentration in the Preparation should be regularly monitored by an automatic in-line DPD TRO sensor to check whether the possible chlorate concentration would reach the criteria mentioned above (< 23 g/L as chlorate). Also, the Group recommended that a finalized procedure should be developed to the satisfaction of the Administration together with an operating manual to control the temperature of the Preparation.

11.4.3 The Group noted that sodium sulfite as a 10% solution would be stored on board. The Group recommended that the safe storage and handling of this product, along with the methodology for making up the neutralizer solution, be detailed in the operating manual for the BWMS.

11.4.4 According to the experience of the Group, the volume of the neutralizer solution needed appears to be high for this BWMS. Therefore, the Group recommended that it should be confirmed that the tank of the neutralizer Preparation is of a sufficient size to accommodate the discharge operation as intended.

11.4.5 Given the nature of the Active Substance and its proposed storage on board, the Group recommended that there was a need by the applicant to consider and incorporate elements of the appropriate safety advice given by the IMDG Code and IBC Code into the operating manual.

11.4.6 The Group recommended that adequate skin and eye protection should be used during loading of the Preparation due to its corrosive effects on the skin and eyes.

11.4.7 The Group recommended that adequate respiratory protective devices, i.e. reusable mask with gas/vapour filter, should be used during ballast water sampling and ballast tank inspection to prevent unacceptable long-term risks to the port State control officers performing sampling and to the crew performing inspection.

11.4.8 The Group recommended that appropriate procedures be developed for tank entry to prevent unacceptable risks to the crew, including:

- .1 emptying of the ballast tank and thereby replacing the atmosphere in the tank;
- .2 full ventilation of the ballast tank prior to personnel entry;
- .3 continuous ventilation during tank entry;
- .4 respiratory protection through wearing RPE, i.e. reusable mask with gas/vapour filter; and
- .5 skin and eye protection.